Guidelines for Controlling Occupational Exposure to Hazardous Drugs

TG 149

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GUIDELINES FOR CONTROLLING OCCUPATIONAL EXPOSURE TO HAZARDOUS DRUGS

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PART I

GENERAL INFORMATION

CHAPTER 1

INTRODUCTION

1-1. PURPOSE. This revision explains the safety and health guidelines for preventing occupational exposure to hazardous drugs (HDs). In addition to the safety precautions listed in this technical guide (TG), health care workers (HCWs) should always consult the drug manufacturer's data or Material Safety Data Sheets (MSDSs) to learn additional, detailed safety precautions for each HD present in their work area(s).

1-2. REFERENCES. Appendix A provides a list of references.

1-3. BACKGROUND.

a. A select number of drugs can be healing to patients but could be harmful to exposed HCWs. Cytotoxic drugs (CDs) make up the majority of the HDs. Other potential HDs include aerosolized drugs, anesthetic gases, estrogens, opiates, and investigational drugs. Occupational exposure to HDs could possibly cause serious adverse health effects, including genetic damage, cancer, birth defects, fertility problems, and organ toxicity. Specifically--

(1) CDs.

(a) CDs or antineoplastic drugs inhibit cell growth and fight cancer. Conversely, many of these agents are also known or suspected human carcinogens. Several studies document deoxyribonucleic acid damage and suggest an increased risk of leukemia and related cancers in persons who received certain types of CDs for the treatment of their cancers. Although some older case reports and studies suggested that nursing personnel preparing CDs without the use of personal protective equipment (PPE) had increased risks of spontaneous abortions, ectopic pregnancies, and children with birth defects, the risks to HCWs in the day-to-day practice of cancer treatment today is unknown.

(b) Part II (chapters 4 through 11) of this TG describes safety precautions for preventing occupational exposure to CDs.

Use of trademarked names does not imply endorsement by the U.S. Army but is intended only to assist in identification of a specific product.

(2) Aerosolized Drugs.

(a) Pentamidine is used to treat *Pneumocystis carinii* pneumonia in immunosuppressed patients, and ribavirin is used to treat severe respiratory syncytial virus in infants and young children. HCWs exposed to aerosolized pentamidine (AP) and ribavirin have noted symptoms of respiratory and eye irritation, sharp pains around the eyes and nose, and headaches.

(b) Part III (chapters 12 and 13) of this TG describes safety precautions for preventing occupational exposure to these two aerosolized drugs.

(3) Anesthetic Gases.

(a) Anesthetic gases, such as nitrous oxide, halothane, enflurane, methoxyflurane, sevoflurane, and isoflurane, are used to anesthetize patients who are undergoing surgery. Exposure to waste anesthetic gases (WAG) may cause drowsiness, headache, nausea, fatigue, and impaired judgement and coordination. Chronic exposure to WAG has been associated with infertility, infants with low birth weight and congenital abnormalities, and an increased risk of spontaneous abortion in exposed female HCWs and the wives of exposed male HCWs.

(b) Safety precautions for preventing occupational exposure to WAG are described in Technical Bulletin, Medical (TB MED) 510.

(4) Methyl Methacrylate.

(a) Methyl methacrylate is used in surgery and dentistry adhesives. Dermal exposure to and inhalation of methyl methacrylate vapors has been shown to cause contact dermatitis and occupational asthma. Also, studies in animals have demonstrated teratogenicity and mutagenicity.

(b) Supervisors and HCWs should consult the manufacturer's data or MSDSs to learn the detailed safety precautions for preventing occupational exposure to methyl methacrylate.

(5) Estrogens and Opiates.

(a) Estrogens and opiates have caused a variety of adverse health effects in workers in the pharmaceutical manufacturing industry.

(b) Supervisors and HCWs should consult the manufacturer's data or MSDS to learn the detailed safety precautions for preventing occupational exposures to these types of agents.

(6) Investigational Drugs.

(a) Investigational drugs are drugs that are under review in clinical studies. HCWs should handle all investigational drugs with caution since their hazards may not be fully known.

(b) Supervisors and HCWs should consult the manufacturer's data or MSDSs to learn the detailed safety precautions for preventing occupational exposures to these agents.

b. Table 1-1 (located at the end of this chapter) lists, by chemical/generic name, the drugs commonly considered hazardous; however, this list is not exhaustive. Army military treatment facility (MTF) commanders should designate a multidisciplinary team of pharmacy/toxicology, occupational health, industrial hygiene, and other trained professionals to identify all HDs used in their MTF.

(1) The Occupational Safety and Health Administration (OSHA) recommends that the team consider the following characteristics when deciding to designate a drug as hazardous:

(a) The American Hospital Formulary Service Drug Information lists the drug as Therapeutic Category 10:00 (antineoplastic).

(b) The drug manufacturer suggests special isolation techniques when HCWs handle, administer, or discard the drug.

(c) The drug is a known--

1. Human mutagen, carcinogen, teratogen, or reproductive toxicant.

2. Animal carcinogen or teratogen.

(d) The drug is known to be acutely toxic to an organ system.

(2) Another method for identifying potentially HDs and for developing handling procedures for them is described in a paper titled "Pharmaceuticals as Hospital Hazards: Managing the Risks" (see appendix A).

c. Trained professionals may exclude a drug if it is "generally regarded as safe" (GRAS). This means that even though a drug has toxic properties, there is little or no documented evidence that it presents an occupational hazard. However, hospitals should cancel a drug's GRAS status when new evidence shows that an occupational hazard exists. In addition, hospitals may exclude a drug when there is no potential for occupational exposure. For example, CDs in solid tablet or pill form may be exempted when HCWs administer them directly to patients.

d. Health risk is based on the drug's toxicity and the extent of the HCW's exposure. Workers risking occupational exposure include pharmacists, nurses, physicians, respiratory therapists, and other HCWs who prepare, administer, transport, handle, and dispose of HDs. Most occupational exposures occur when HCWs inhale drug aerosols or droplets, absorb the drug through the skin (including needlesticks), and ingest the drug through contact with contaminated foods, food containers, or tobacco products.

e. To date, OSHA has not set specific permissible exposure limits or standards for all HDs. However, OSHA has issued guidelines urging health care employers to set up an HD safety and health plan (HDSHP) and to keep occupational exposures as low as possible. A gross violation of such guidelines or equivalent procedures could result in a citation under the General Duty Clause of the Occupational Safety and Health Act (Public Law (PL) 91-596).

f. Safety precautions that control occupational exposure to HDs include effective engineering controls, administrative controls, safe work practices, and PPE.

(1) Engineering controls are preferred since they control worker exposures by containing the contaminants at their source and by reducing the quantity of contaminants released into the work environment. Biological safety cabinets (BSCs), negative chamber booths, and sharps containers are examples of engineering controls that enclose a process or a hazard to prevent occupational exposure to HDs.

(2) Administrative controls are used to control worker exposures by reducing the time that they spend in contaminated areas. Examples of administrative controls include job rotation, job transfer, and modified work schedules.

(3) Safe work practices are work procedures designed to prevent worker injuries or exposures to known hazards. Examples of safe work practices include good housekeeping, sanitation and hygiene, and handling techniques that minimize or prevent generation of aerosols or dusts.

(4) PPE must be used in conjunction with engineering and administrative controls and safe work practices whenever work exposures cannot be sufficiently reduced to acceptable limits. Examples of PPE include safety glasses or goggles, face shields, gloves, gowns, and respirators.

1-4. TECHNICAL ASSISTANCE. Requests for additional assistance and guidance may be addressed to Commander, U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM), ATTN: MCHB-TS-OIM, Aberdeen Proving Ground, MD 21010-5403, or by calling Defense Switching Network (DSN) 584-2439.

Table 1-1. DRUGS COMMONLY CONSIDERED HAZARDOUS

CHEMICAL/GENERIC NAME	SOURCE
ALTRETAMINE	C
AMINOGLUTETHIMIDE	A
AZATHIOPRINE	ACE
BLEOMYCIN	ABC
BUSULFAN	ABC
CARBOPLATIN	ABC
CARMUSTINE	ABC
CHLORAMBUCIL	ABCE
CHLORAMPHENICOL	E
CHLOROTRIANISENE	B
CHLOROZOTOCIN	E
CISPLATIN	ABCE
CLADRIBINE	A
CYCLOPHOSPHANHDE	ABCE
CYCLOSPORIN	E
CYTARABINE	ABC
DACARBAZINE	ABC
DACTINOMYCIN	ABC
DAUNORUBICIN	ABC
DAUNORUBICIN CITRATE, LIPOSOMAL	A
DEXRAZOXANE	A
DIETHYLSTILBESTROL	BE
DOCETAXEL	A
DOXORUBICIN HC1, LIPOSOMAL	A
DOXORUBICIN	ABCE
ESTRADIOL	B
ESTRAMUSTINE	AB
ETHINYLESTRADIOL	B
ETOPOSIDE	ABC
FLOXURIDINE	AC
FLUDARABINE	A
FLUOROURACIL	ABC
FLUTANUDE	BC
GANCICLOVIR-AD	AD
GEMCITABINE	A

Table 1-1. DRUGS COMMONLY CONSIDERED HAZARDOUS (Continued)

CHEMICAL/GENERIC NAME	SOURCE
GOSERELIN ACETATE	A
HYDROXYUREA	ABC
IDARUBICIN	AC
IFOSFANHDE	ABC
INTERFERON-A	BC
IRINOTECAN HYDROCHLORIDE	A
ISOTRETINOIN	D
L-ASPARAGINASE	ABC
LEUPROLIDE	BC
LEVAMISOLE	C
LOMUSTINE	ABCD
MECHLORETHAMINE	BC
MEDROXYPROGESTERONE	B
MEGESTROL	BC
MELPHALAN	ABCE
MERCAPTOPURINE	ABC
METHOTREXATE	ABC
MITOMYCIN	ABC
MITOTANE	ABC
NHTOXANTRONE	ABC
NAFARELIN	C
PACLITAXEL	A
PEGASPARAGASE	A
PENTOSTATIN	A
PIPOBROMAN	C
PLICAMYCIN	BC
PROCARBAZINE	ABCE
RIBAVIRIN	D
STREPTOZOCIN	AC
TAMOXIFEN	BC
TENIPOSIDE	A
TESTOLACTONE	BC
TFHOGUANINE	ABC
THIOTEPA	ABC
TOPOTECAN HYDROCHLORIDE	A
TRIMETREXATE	A

Table 1-1. DRUGS COMMONLY CONSIDERED HAZARDOUS (Continued)

CHEMICAL/GENERIC NAME	SOURCE
URACIL MUSTARD	ACE
VIDARABINE	D
VINBLASTINE	ABC
VINCRISTINE	ABC
VINDESINE	A
VINORELBINE TARTRATE	A
ZIDOVUDINE	D

SOURCES:

A National Institutes of Health, Clinical Center Nursing Department
B Physicians' Desk Reference
C American Hospital Formulary, Antineoplastics
D Johns Hopkins Hospital
E International Agency for Research on Cancer

NOTE: This list is not exhaustive. See paragraph 1-3 for additional procedures that may be used to identify HDs.

CHAPTER 2

HAZARDOUS DRUG SAFETY AND HEALTH PLAN

2-1. GENERAL. Guidelines for setting up and carrying out an HDSHP are found in OSHA Technical Manual, OSHA Instruction TED 1.15, section V, chapter 3. These guidelines mirror the latest information published by the American Society of Hospital Pharmacists. Additional guidance in setting up an HDSHP is available in the Joint Commission on Accreditation of Healthcare Organizations' *Comprehensive Accreditation Manual for Hospitals: The Official Handbook* and in Army Regulation (AR) 40-2.

2-2. PERSONNEL.

a. HD Officer. Army MTF commanders should appoint an individual to set up and carry out the HDSHP. OSHA believes that ideal candidates for this position include pharmacists, safety and health representatives, nurses, and industrial hygienists. More important, the HD officer should know the safety and health risks associated with HDs used in the MTF and the safety precautions that will prevent or minimize occupational exposure(s).

b. HD Committee. Commanders should establish a committee to formulate policies for evaluating, selecting, procuring, distributing, and using therapeutic agents and pharmaceuticals as well as recommending education and training programs for all exposed HCWs. To carry out these responsibilities effectively, the committee should include representatives from the medical and nursing staffs; pharmacy; occupational or preventive medicine (PVNTMED); hospital education and training; safety; and logistics, including supply, housekeeping, and maintenance.

2-3. HAZARDOUS DRUG SAFETY AND HEALTH PLAN COMPONENTS. Appendix B contains a sample HDSHP. At a minimum, the HDSHP should address the following elements:

a. Hazard Identification and Safety Precautions. The HDSHP should describe the methods used to systematically identify, evaluate, and prevent or control work place hazards.

(1) Identification and evaluation methods include program assessments; job hazard analyses; general safety inspections; and reviews of employee reports of unsafe/unhealthy working conditions, accident and incident reports, and OSHA No. 200 (Log and Summary of Occupational Injuries and Illnesses) log form entries.

(2) Prevention and control methods include engineering and administrative controls, safe work practices, and PPE that will prevent or minimize occupational exposure(s).

b. Ventilation Systems. Ventilation systems, such as BSCs, isolation rooms, and negative chamber booths, contain and remove hazardous aerosols only when they operate properly. Therefore, the HDSHP should specify the procedures for carrying out regular certification and maintenance checks of ventilation systems by qualified individuals. In addition, the HDSHP should include a requirement for HCWs to verify that ventilation systems are operational before starting any work or procedures.

c. Standing Operating Procedures (SOPs). The HDSHP should reference any SOPs related to HD receipt, storage, preparation, administration, and disposal. Some related SOPs may include hazard communication (HAZCOM), emergency preparedness, hazardous material (HAZMAT) spill prevention and response, waste disposal, linen management, medical surveillance, accident reporting, and departmental-specific HD SOPs. Supervisors of affected HCWs should keep copies of the HDSHP and reference SOPs in locations that are readily available to all HCWs, including temporary workers, contractors, and trainees.

d. Investigational Drugs. Use of investigational drugs requires compliance with established clinical investigation and human use review regulations and prior written approval by the Army's Surgeon General or his designee. AR 40-7 contains detailed policies for using investigational drugs.

e. Information and Training Program.

(1) All HCWs having potential occupational exposure to HDs must receive adequate training before they assume their job duties. Potentially exposed HCWs must understand the safety and health hazards of HDs, and they must know the safe work practices to prevent occupational exposure(s).

(2) Supervisors of potentially exposed HCWs should be trained to--

(a) Regularly evaluate the work area and work procedures to detect safety and health hazards.

(b) Make sure that control measures are functional and properly used.

(c) Reinforce worker training.

(3) Chapter 3 addresses information and training requirements in greater detail.

f. Medical Surveillance and Examinations.

(1) The HDSHP should reference the MTF's occupational health policies for providing preplacement, routine, and termination or transfer examinations for HCWs exposed to HDs. In addition, the HDSHP should reference procedures for providing medical examinations following acute exposures to HDs. Any occurrence of exposure-related disease or adverse health effects should initiate an immediate investigation into the effectiveness of the safety precautions currently in use.

(2) Chapter 4 addresses medical surveillance and examination requirements in greater detail.

g. Recordkeeping. Army MTFs should keep records to show that the HDSHP is carried out as it was designed. At a minimum, records should include the results of annual program evaluations, maintenance records for ventilation systems, workers' medical records and education and training records, and, if applicable, investigational HD approvals and reports.

h. Effectiveness Evaluations.

(1) The HD officer should--

(a) Evaluate the HDSHP for effectiveness at least annually.

(b) Update the HDSHP as necessary.

(2) The HD committee and the MTF safety committee should--

(a) Review the annual effectiveness evaluations; departmental-specific HD SOPs; and periodic reports of incidents, injuries, and equipment failures.

(b) Suggest ways to improve the program as needed.

(3) Work area supervisors should update departmental-specific policies and procedures as needed, but at least once every 3 years.

CHAPTER 3

TRAINING AND INFORMATION

3-1. ORIENTATION AND REFRESHER TRAINING.

a. All HCWs involved in any aspect of handling HDs must be trained in the hazards of the HDs in their work area(s) and the safe work practices to prevent occupational exposure(s). Some job classifications of affected HCWs include shipping/receiving personnel, physicians, nurses, pharmacists, respiratory therapists, housekeepers, maintenance workers, hazardous waste handlers, and HAZMAT spill responders.

b. Supervisors of affected HCWs (i.e., temporary, permanent, and contractor) must--

(1) Ensure that HCWs under their supervision attend orientation before beginning any work with HDs and that their attendance is documented.

(2) Reassess HCWs' knowledge and competency after the initial orientation, when new hazards or techniques are introduced into the work area, and yearly thereafter. Competency assessments should include written examinations, an observed demonstration of safe handling skills, or a combination of both.

c. Orientation must be sufficient to meet the HAZCOM or "worker-right-to-know" statutes and regulations and cover the--

(1) Known risks of handling HDs.

(2) Relevant techniques and procedures for handling HDs.

(3) Proper use of PPE and waste disposal materials.

(4) Spill cleanup procedures.

(5) Medical policies (including those dealing with pregnancy and with HCWs actively trying to conceive children).

3-2. HAZARD COMMUNICATION.

a. Applicability. HCWs who risk occupational exposure to HDs are covered by the OSHA's HAZCOM standard (section 1200, part 1910, title 29, Code of Federal Regulations (29 CFR 1910.1200)).

b. HAZCOM Program Requirements.

(1) Written Program and Inventories. The written HAZCOM program must explain the MTF's procedures for maintaining warning labels and MSDSs, conducting employee information and training, performing nonroutine tasks, and sharing information with contract workers. In addition, the written program must include a list of all the hazardous chemicals, including HDs, used at the facility.

(2) Warning Labels. Original packages containing HDs must list the name of the material, the physical and health hazards, and the name of the manufacturer.

(3) MSDSs.

(a) Drug manufacturers and importers must--

1. Obtain or develop MSDSs for each HD that they produce or import.

2. Send a copy of the MSDS to their customers with all initial shipments.

(b) Army MTFs must--

1. Have an MSDS on hand for each HD that they use.

2. Make sure that the MSDSs are readily available to affected HCWs.

(4) Information and Training.

(a) Work area supervisors should review the MSDS for each HD and explain the following essential information to HCWs:

1. Health hazards.

2. Primary exposure routes.

3. Carcinogenic evaluations.

4. Acute exposure treatment.

5. Chemical inactivators.

6. Solubility, stability, and volatility.

(b) HCWs must know the--

1. Requirements and location of the MTF's HAZCOM standard.

2. Operations or procedures in their work area(s) where HDs are present.

3. Location of SOPs regarding HDs.

(c) HCWs must be trained in the--

1. Ways to detect the presence or release of HDs in their work area(s).

2. Physical, health, and reproductive hazards of HDs in their work area(s).

3. Engineering controls, administrative controls, safe work practices, and PPE used to prevent exposure(s).

4. Emergency spill response procedures.

5. Use and care of engineering controls and PPE.

6. Proper disposal of HD wastes.

3-3. RECORDKEEPING.

a. HAZCOM and HD training records should be maintained for 3 years from the date of training.

b. HD training records should include the following:

(1) Training date.

(2) Summary of the training session, such as a lesson plan or training outline.

(3) Name(s) and qualifications of the instructor(s).

(4) Name(s) and job title(s) of all HCWs attending the training session.

PART II

CYTOTOXIC DRUGS

CHAPTER 4

MEDICAL SURVEILLANCE

4-1. PREPLACEMENT AND TRANSFER OR TERMINATION EXAMINATIONS.

a. The following personnel should have preplacement and transfer or termination medical examinations:

(1) All HCWs with potential for exposure to CDs through preparation, administration, housekeeping, waste disposal, transport, storage, or spill cleanup.

(2) Maintenance and service personnel with potential for exposure to CDs while performing repairs on BSCs, replacing BSC filters, or conducting BSC certification.

b. Physicians should tailor the medical examination and laboratory studies to the HCW's potential for exposure and the specific toxic profiles of agent handled (e.g., hematologic studies for antineoplastic agents).

4-2. PERIODIC EXAMINATION.

a. All personnel working with CDs should receive a medical examination on a yearly basis or every 2 to 3 years, at the discretion of the occupational medicine physician; and an incidental examination as required (i.e., after an acute exposure).

b. These examinations may detect changes in--

(1) The HCW's general health, as might be affected by subsequent exposure to CDs.

(2) Specific diagnoses secondary to exposure to CDs.

4-3. ACUTE EXPOSURES.

a. Acute exposures include, but are not limited to--

(1) A needle-stick from a needle attached to a syringe or intravenous (IV) catheter containing the CD.

(2) A spill or splash on exposed skin or in the eye(s).

(3) Ingestion resulting from inadvertent hand contact with CDs when handling food, drink, cosmetics, and smoking materials.

(4) Inhalation of aerosols or droplets.

b. First aid for an acute exposure requires immediate action to include decontamination and medical care or evaluation.

4-4. PERSONNEL CONTAMINATION.

a. Treat overt contamination of gloves or gown and direct skin or eye contact as follows:

(1) Immediately remove contaminated PPE and discard disposable items in a CD waste container.

(2) Wash contaminated skin with soap and water. For splashes to the eye(s), rinse the affected eye(s) with water for at least 15 minutes.

(3) Refer to the manufacturer's MSDS for additional emergency and first-aid procedures.

(4) Follow-up with medical attention, especially for inhalation of CDs in powder form.

b. Following an acute exposure, the treating physician must document acute exposure evaluations in the HCW's health record. Also, the HCW's immediate supervisor must investigate the accident according to the MTF's accident reporting procedures and send a copy of the accident report to the safety officer.

4-5. PREGNANCY. Workers starting any job that requires routine handling of CDs should be fully informed of the potential reproductive and other health hazards. Additionally, HCWs who are pregnant, breast-feeding, or are trying to conceive a child should be given the option of being transferred to other comparable duties that do not involve handling CDs.

4-6. EMPLOYEE REGISTRY.

a. The MTF's occupational health department should keep a permanent registry, to facilitate future epidemiologic studies, of all HCWs who handle CDs. HCW's exposure records should include--

(1) The HCW's exposure levels or anticipated exposure levels, including background data necessary to interpret the results. In the absence of environmental sampling data, include--

(a) Records of drugs and quantities handled.

(b) Hours spent handling these drugs per week.

(c) Number of preparations/administrations per week.

(2) The engineering controls in place and PPE used by the HCW, especially at the time of exposure.

(3) A description of the HCW's duties.

(4) The pertinent results from the HCW's previous medical examinations.

b. The HCW's medical records and exposure records must be kept for the duration of employment plus 30 years. HCWs must have access to their medical records.

CHAPTER 5

ENGINEERING CONTROLS AND SAFETY EQUIPMENT

5-1. BIOLOGICAL SAFETY CABINETS.

a. Selection.

(1) Class II and Class III BSCs that meet the current National Sanitation Foundation (NSF) International Standard 49 are preferred when working with CDs because the--

(a) Inward airflow into the BSC's front grill protects the HCW.

(b) Downward laminar flow of high efficiency particulate air (HEPA)-filtered air within the BSC protects the product.

(c) HEPA filters installed in the exhaust ducts protect the environment.

(2) Class II, Types B1, B2, and B3; and Class III BSCs offer the greatest protection since they do not recirculate air back into the work area. Class II, Type A, BSCs may also be used; however, they may not be as protective as the others since they discharge air through a HEPA filter back into the work area.

(a) Class II, Type A, BSCs recirculate about 70 percent of the cabinet's air through HEPA filters back into the BSC and discharge 30 percent of the air through a HEPA filter into the work area (see figure 5-1 located at the end of this chapter). The BSC's internal blower draws air through the front grill to maintain an average inflow velocity of at least 75 feet per minute (fpm) through the work area access opening. The downward airflow splits just above the work surface with the front grill drawing in part of the air and the rear grill drawing in the rest of the air. The exhaust from Class II, Type A, BSCs may be ducted outside of the building with a thimble or canopy hood (see figure 5-2 located at the end of this chapter). Ductless Class II, Type A, BSCs should never be used when working with volatile chemicals because build-up of chemical vapors can cause a fire or explosion.

(b) Class II, Type Bl, BSCs recirculate 30 percent of the cabinets's air and discharge 70 percent of the air through HEPA filters to the outside (see figure 5-3 located at the end of this chapter). The BSC's blower draws air through the BSC's work area access opening at a minimum velocity of 100 fpm. As with Class II, Type A, BSCs, the air splits over the work surface with the front grill drawing in 30 percent of the air and the rear grill

drawing in and exhausting 70 percent of the air. Therefore, operations that may generate hazardous chemical vapors or particulates should be conducted towards the rear of the BSC. Class II, Type B 1, BSCs must be hard-ducted, preferably with their own dedicated exhaust system. The exhaust system and plenums should be under negative pressure.

(c) Class II, Type B2, BSCs discharge 100 percent of the cabinet's air through HEPA filters to the outside (see figure 5-4 located at the end of this chapter). The BSC's blower draws in room air or outside air at the top of the BSC and passes it through a HEPA filter and down into the work area. The exhaust system draws in air through the front and the rear grills, capturing the supply air plus drawing in additional room air through the BSC's work area access opening at a minimum inflow velocity of 100 fpm. The exhaust system is similar to those used for Class II, Type Bl, BSCs. Class II, Type B2, BSCs are preferred when working with CDs because all air is exhausted directly outside.

(d) Class II, Type B3, BSCs are ducted Class II, Type A, BSCs. These BSCs recirculate 70 percent of the cabinet's air and discharge 30 percent of the air through HEPA filters to the outside (see figure 5-5 located at the end of this chapter). The inward airflow at the work area access opening should be maintained at 100 fpm.

(e) Class III BSCs are gas-tight BSCs. These BSCs are equipped with permanently closed windows and heavy-duty rubber gloves attached to ports to allow for manipulation of materials inside the BSC (see figure 5-6 located at the end of this chapter). Class III BSCs are primarily designed for work with biosafety level 4 microbiological agents and are rarely used in hospitals.

b. Exhaust Systems.

(1) If possible, keep the BSC's exhaust fan on at all times (24 hours a day, 7 days a week).

(2) If the exhaust fan must be turned off, decontaminate the BSC before reuse. Also, let the fan operate 3 to 5 minutes before beginning work to allow the BSC to purge any particulates present inside the BSC.

(3) When separate fans are used for recirculated and exhaust air, the fans must be interlocked so that--

(a) If the exhaust fan fails, the supply fan will shut off and trigger an alarm.

(b) If the supply fan fails, the exhaust fan must continue to operate after the alarm sounds.

(4) If the BSC is exhausted by a remote blower, the unit must be equipped with a sensor, an audible alarm, and a warning light to indicate when the remote blower is nonoperational.

(5) Fans and exhaust blowers should be connected to the MTF's emergency power supply to maintain critical operations during a power outage.

(6) If the BSC is vented to the outside--

(a) Discharge the exhaust air at an appropriate height, with a minimum stack height of 10 feet.

(b) Prohibit rain caps and other obstructions on the exhaust ducts.

(c) Direct the airflow away from air-intake units.

(d) Provide a stack velocity of approximately 3000 fpm.

c. Placement.

(1) Install BSCs in the rear of the room away from entrances, traffic, open windows, air supply registers, and laboratory equipment that create air movement.

(2) If possible, maintain a 12-inch clearance behind and on each side of the BSC to allow easy access for maintenance. A 12- to 14-inch clearance may be required above the BSC to allow accurate air velocity measurement across the exhaust filter surface.

d. Maintenance.

(1) Follow the manufacturer's instructions and the specifications listed in the NSF International Standard 49 for maintaining and evaluating BSCs. In general, BSCs should be certified only by qualified technicians who are trained in BSC design theory. Certification should occur upon initial installation, **EVERY 6 MONTHS thereafter,** and whenever the BSC is moved or repaired.

(2) Certified maintenance workers who maintain BSCs used for CD preparation should--

(a) Receive information and training as discussed in chapter 3.

(b) Wear the following PPE as described in chapter 6:

1. Two pairs of disposable surgical latex gloves or gloves made of polyvinyl chloride under the latex gloves, a pair of 3-4 millimeter (mm) thick gloves designed specifically for handling CDs, or gloves made of an alternate material recommended by the manufacturer.

2. A protective disposable gown.

3. Either a National Institute for Occupational Safety and Health (NIOSH)-approved full facepiece respirator appropriate for the hazard; or a less than full facepiece respirator, provided the employee wears a plastic face shield or splash goggles complying with American National Standards Institute (ANSI) Z87.1-1989 (see paragraphs 6-3 and 6-4).

(c) Change HEPA filters when they restrict airflow. Maintenance workers should--

1. Place a "DO NOT USE – CONTAMINATED" label on the BSC.

2. Change the filter using a "bag in - bag out" type filter.

3. Dispose of filters as a CD waste.

e. Cleaning and Disinfecting. Work area supervisors should set up a cleaning schedule according to the BSC manufacturer's instructions. HCWs should always decontaminate BSCs before they are moved, serviced, or certified and whenever a spill occurs. HCWs should--

(1) Receive information and training as discussed in chapter 3.

(2) Wear the following PPE as described in chapter 6:

(a) Two pairs of disposable surgical latex gloves or gloves made of polyvinyl chloride under the latex gloves, a pair of 3-4 mm thick gloves designed specifically for handling CDs, or gloves made of an alternate material recommended by the manufacturer.

(b) A protective disposable gown.

(3) Keep the exhaust fan/blower on and the sash down during decontamination. If the sash must be lifted during the process, the HCW must wear either a NIOSH-approved full facepiece respirator appropriate for the hazard; or a less than full facepiece respirator,

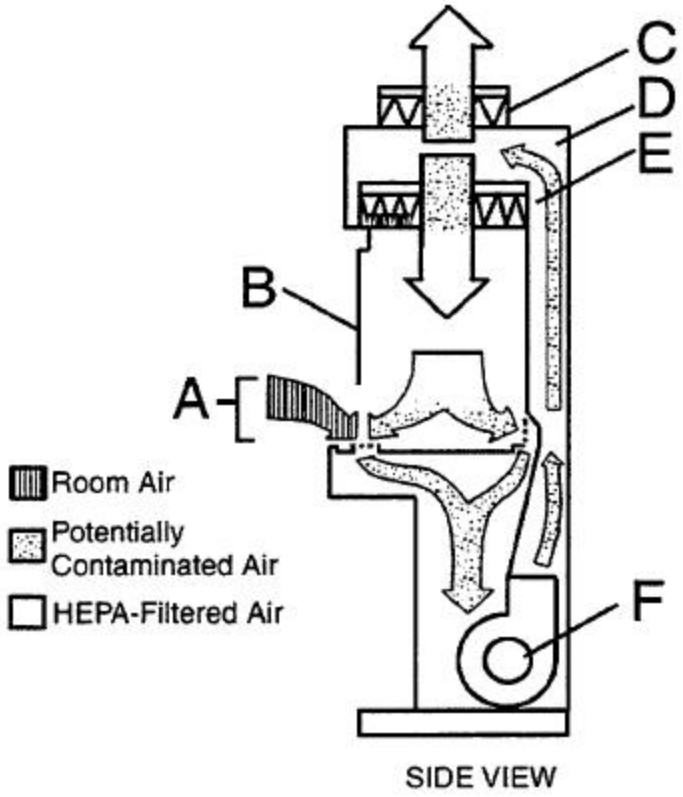
provided the employee wears a plastic face shield or splash goggles complying with ANSI Z87.1-1989 (see paragraphs 6-3 and 6-4).

(4) Decontaminate surfaces with water and detergent followed by a thorough rinsing with clean water. Decontamination should proceed from the least to the most contaminated areas. Lift and clean the back and sump located under the removable work trays. Clean the drain spillage area at least twice, since it may be heavily contaminated.

(5) Dispose of materials used during decontamination as a CD waste.

5-2. SINKS. Install a sink for hand washing in the CD preparation area. Stock plenty of paper towels and soap near the sink. Require HCWs to wash their hands before and after gloving and before leaving the preparation area.

5-3. EMERGENCY EYEWASH STATIONS. Install a stand-alone, plumbed emergency eyewash station, complying with ANSI Z358.1-1998, in the preparation area for immediate flushing of the face and eyes if splashing may occur. HCWs should activate the device at least weekly and let the water run for at least 3 minutes to ensure proper operation and to flush stagnant water from the water supply lines.

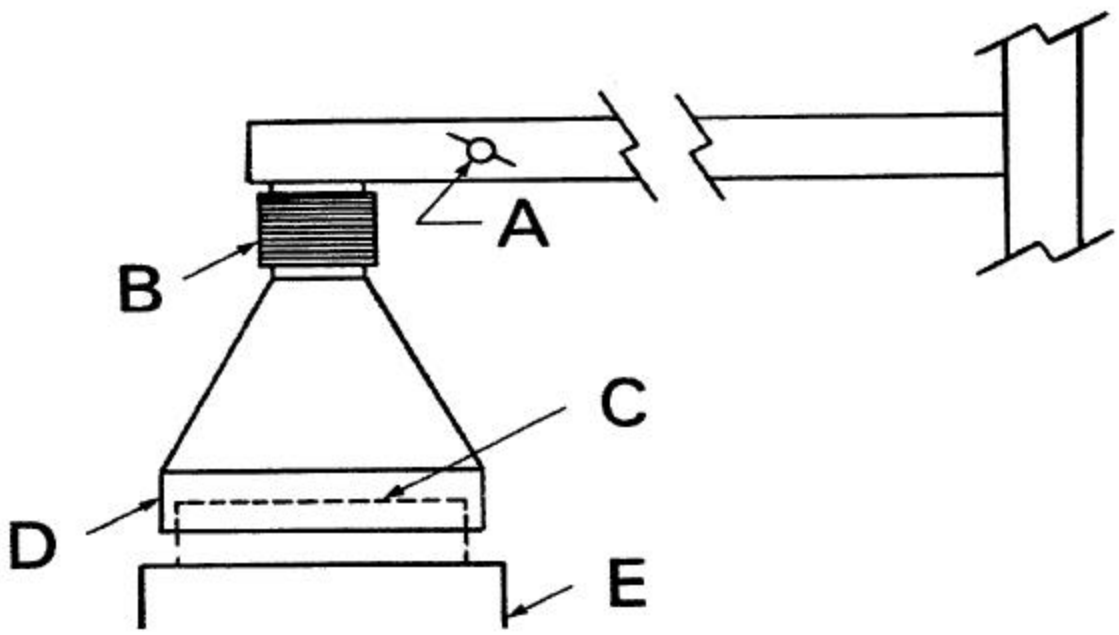


Legend:

A. Front Opening
B. Sash
C. Exhaust HEPA Filter
D. Rear Plenum
E. Supply HEPA Filter
F. Blower

Source: Reprinted from *Primary Containment for Biohazards: Selection, Installation and Use of Biological* Safety *Cabinets,* published by U.S. Department of Health and Human Services (DHHS), Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, September 1995.

Figure 5-1. Class II, Type A, Biological Safety Cabinet



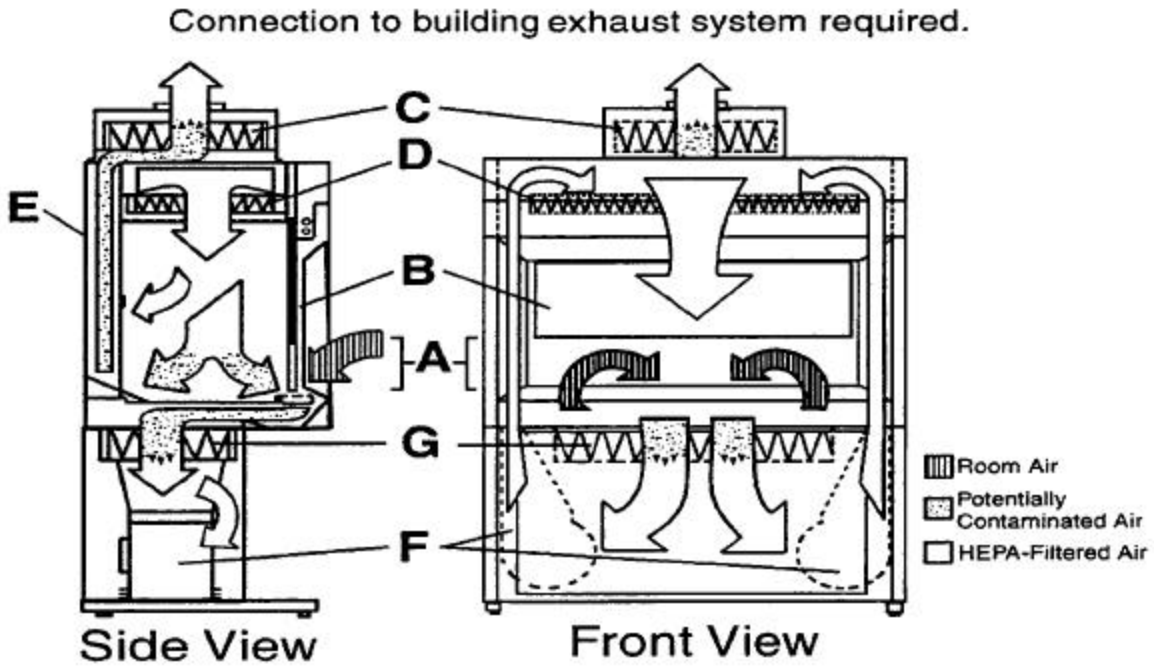
Legend:

- **A. Balancing Damper**
- **B. Flexible Connector to Exhaust System**
- **C. Cabinet Exhaust HEPA Filter Housing**
- **D. Thimble Unit**
- **E. Biological Safety Cabinet**

Note: There is a 1-inch gap between the thimble unit (D) and the exhaust filter housing (C) through which room air is exhausted.

Source: Reprinted from *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets,* published by DHHS, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, September 1995.

Figure 5-2. Thimble Unit for Ducting a Class II, Type A, Biological Safety Cabinet

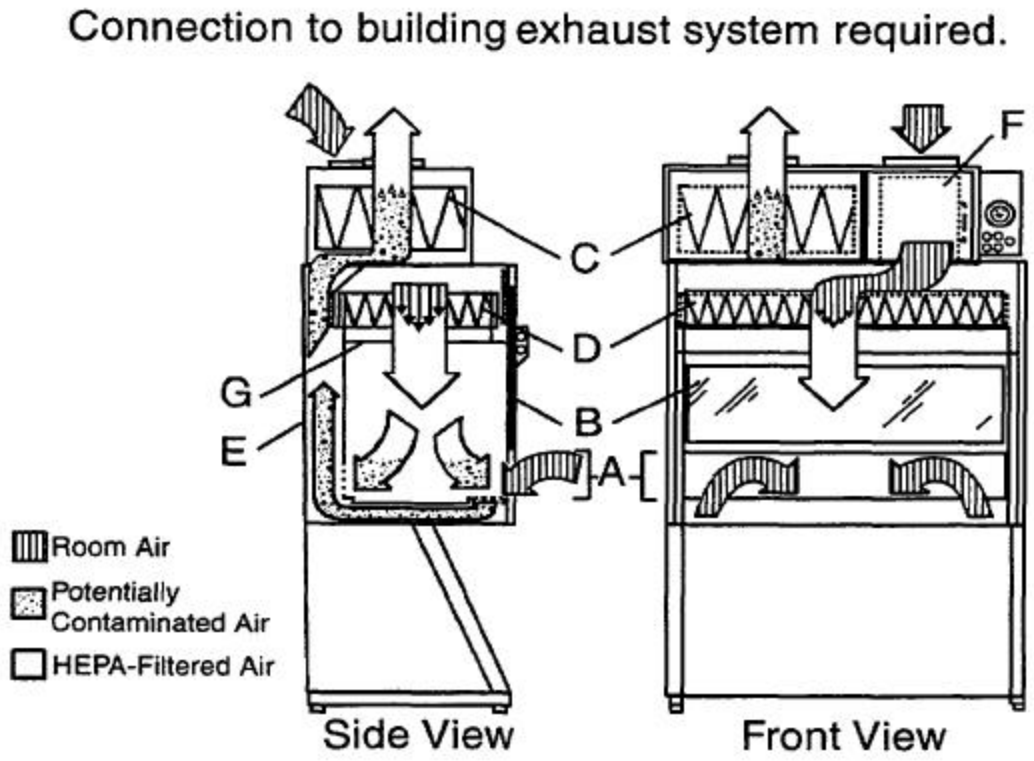


Legend:

- **A. Front Opening**
- **B. Sash**
- **C. Exhaust HEPA Filter**
- **D. Supply HEPA Filter**
- **E. Negative-Pressure Exhaust Plenum**
- **F. Blower**
- **G. Additional HEPA Filter for Supply Air**

Source: Reprinted from *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets,* published by DHHS, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, September 1995.

Figure 5-3. Class II, Type B1, Biological Safety Cabinet



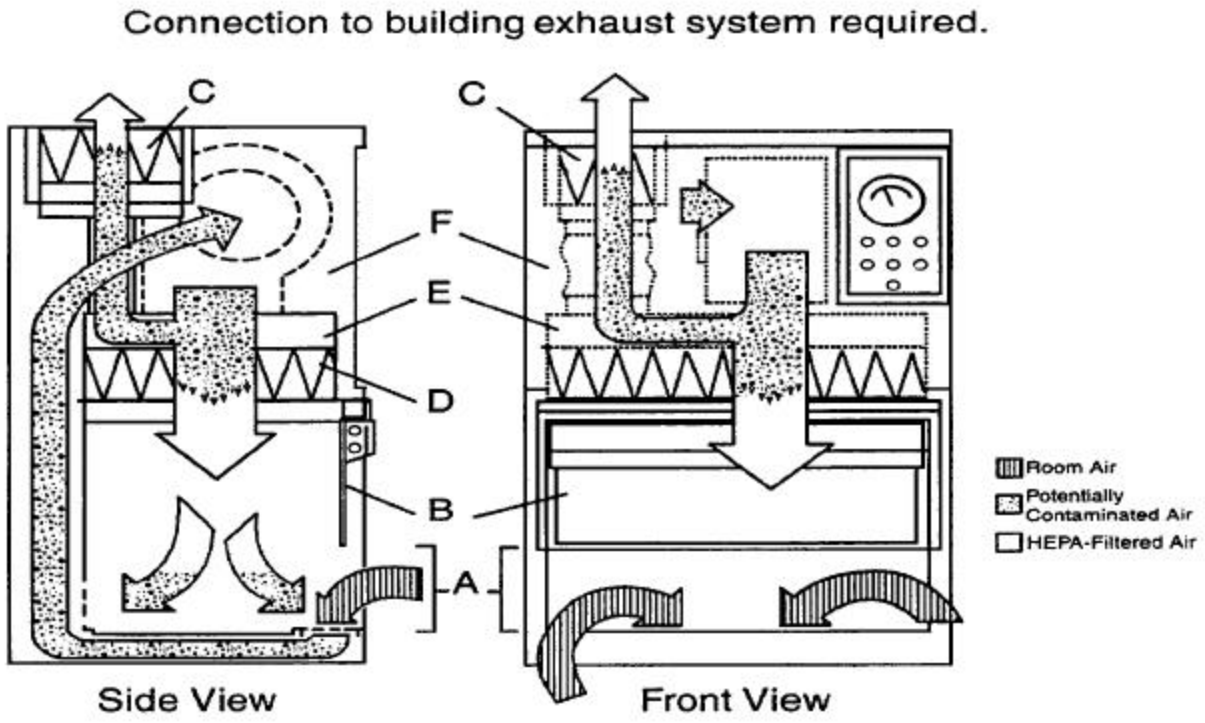
Legend:

- **A. Front Opening**
- **B. Sash**
- **C. Exhaust HEPA Filter**
- **D. Supply HEPA Filter**
- **E. Negative-Pressure Exhaust Plenum**
- **F. Supply Blower**
- **G. Filter Screen**

Note: The carbon filter in the building exhaust is not shown.

Source: Reprinted from *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets,* published by DHHS, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, September 1995.

Figure 5-4. Class II, Type B2, Biological Safety Cabinet

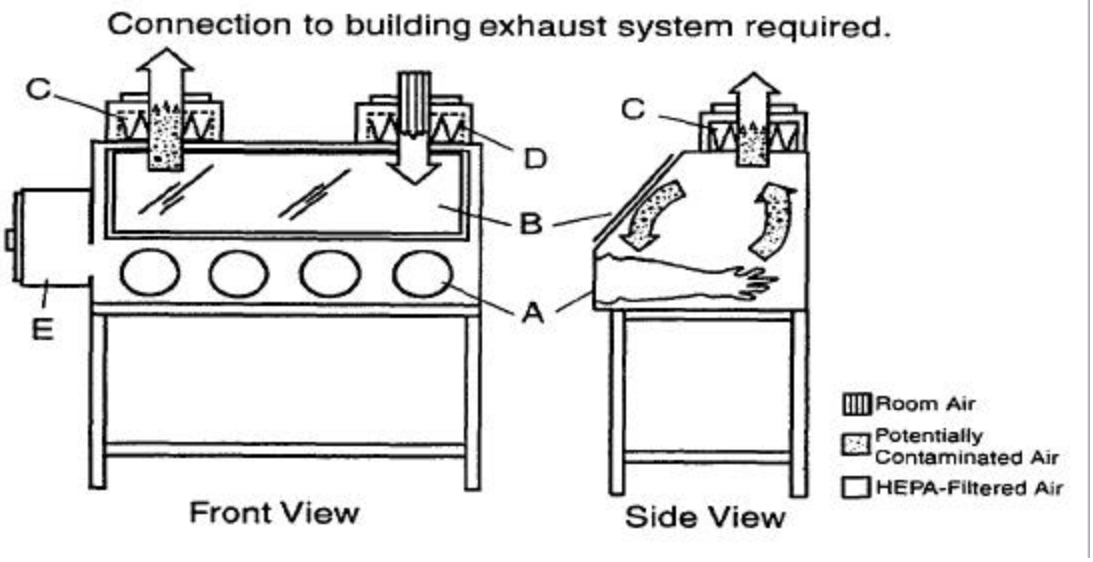


Legend:

- **A. Front Opening**
- **B. Sash**
- **C. Exhaust HEPA Filter**
- **D. Supply HEPA Filter**
- **E. Positive-Pressure Plenum**
- **F. Negative-Pressure Plenum**

Source: Reprinted from *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets,* published by DHHS, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, September 1995.

Figure 5-5. Class II, Type B3, Biological Safety Cabinet



Legend:

A. Glove Ports with O-Ring for Attaching Arm-Length Gloves to BSC
B. Sash
C. Exhaust HEPA Filter
D. Supply HEPA Filter
E. Double-Ended Autoclave or Pass-Through Box

Note: A chemical dunk tank may be installed which would be located beneath the work surface of the BSC with access from above.

Source: Reprinted from *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets,* published by DHHS, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, September 1995.

Figure 5-6. Class III Biological Safety Cabinet

CHAPTER 6

PERSONAL PROTECTIVE EQUIPMENT

6-1. GLOVES. Gloves are the first line of defense, since the hands provide the greatest potential for exposure. HCWs should--

a. Wear two pairs of disposable surgical latex gloves or gloves made of polyvinyl chloride under the latex gloves, a pair of 3-4 mm thick gloves designed specifically for handling CDs, or gloves made of an alternate material recommended by the manufacturer.

b. Change gloves at least hourly and immediately if they are torn, punctured, or become overly contaminated.

c. Wash hands before gloving and after removing gloves.

d. **NEVER** wear contaminated gloves outside the immediate preparation area.

NOTE

Powdered latex gloves should never be used since the powder may absorb CDs. Also, powder-free gloves may reduce exposures to latex protein and reduce the risk of latex allergy. HCWs with known or suspected latex sensitivity should wear gloves made of an alternate material recommended by the CD manufacturer or gloves made of polyvinyl chloride under the latex gloves.

6-2. DISPOSABLE GOWNS. HCWs should--

a. Wear a protective, disposable gown that--

(1) Is made of a lint-free, low permeability fabric (e.g., Saranex®-laminated Tyvek® or polyethylene-coated Tyvek).

®Saranex is a registered trademark of the Dow Chemical Co., Midland, Michigan.
®Tyvek is a registered trademark of the E.I. duPont de Nemours & Co., Wilmington, Delaware.

(2) Has a solid front with back closure.

(3) Has long sleeves with elastic or closed-knit cuffs.

b. Tuck the cuffs under gloves when wearing a single pair of gloves. If gloves are doubled, tuck one glove under the cuff and one glove over the cuff.

c. **NEVER** wear contaminated gowns outside the preparation area.

6-3. RESPIRATORS. Where a BSC is not currently available, and whenever sprays, splashes, or aerosols of HDs may be generated, HCWs should--

a. Wear either a NIOSH-approved full facepiece, air-purifying, particulate respirator; or a less than full facepiece, air-purifying, particulate respirator, provided the employee wears a plastic face shield or splash goggles complying with ANSI Z87.1-1989. Air-purifying, particulate respirators should have a filter designation equal to or greater than N100 (previously HEPA filter). Coordinate respirator and filter selection with the Installation Respiratory Protection Program Manager or PVNTMED service personnel.

b. Clean reusable respirators with mild detergent and clean water after use.

c. NEVER wear surgical masks in place of respirators, since surgical masks DO NOT protect against breathing CD aerosols.

NOTE

Use respirators in accordance with OSHA (29 CFR 1910.134) and Army (AR 11-34) regulations. Select particulate respirator filters in accordance with NIOSH (42 CFR 84).

6-4. FACE SHIELDS AND SPLASH GOGGLES. HCWs should-

a. Wear a plastic face shield or splash goggles complying with ANSI Z87.1-1989 whenever splashes, sprays, or aerosols of CDs may be generated.

b. Clean reusable face shields and splash goggles with mild detergent and clean water after use.

NOTE

Eyeglasses with temporary side shields do not provide adequate protection.

CHAPTER 7

RECEIPT, STORAGE, AND HANDLING

7-1. RESTRICTED AREAS. Limit access to CD storage areas to authorized HCWs only. Also, areas used to store CD-contaminated equipment, trash, and linen should be secured to prevent unauthorized access.

7-2. WARNING SIGNS. Post the CD storage area with--

a. A large warning sign bearing the legend:

"CAUTION--RESTRICTED ACCESS - AUTHORIZED PERSONNEL ONLY"

b. A list of all CDs covered by the MTF's HDSHP.

c. A sign detailing procedures for cleaning up and reporting spills, as well as procedures for providing first aid after accidental skin and eye contact.

7-3. TRAINING AND SUPERVISION. HCWs who receive CDs should receive information and training as discussed in chapter 3, as well as specialized training in--

a. Receiving and storing CDs.

b. Handling and disposing of damaged CD cartons.

7-4. RECEIPT AND STORAGE. HCWs should--

a. Keep MSDSs, a CD spill kit, and waste disposal materials in a readily accessible location in or near the receiving area.

b. Verify that all incoming CD containers have a hazard warning label that meets the OSHA's HAZCOM standard (29 CFR 1910.1200). Also, the shelves and bins where these containers are permanently stored should be labeled with a CD hazard warning sign.

c. Store CDs separately from other medications. To prevent CD containers from falling--

(1) Storage shelves should be equipped with guards.

(2) Containers should be neatly arranged on the shelves or in bins.

7-5. HANDLING DAMAGED CARTONS. When handling damaged cartons, HCWs should--

a. Wear the following PPE as described in chapter 6:

(1) Two pairs of disposable surgical latex gloves or gloves made of polyvinyl chloride under the latex gloves, a pair of 3-4 mm thick gloves designed specifically for handling CDs, or gloves made of an alternate material recommended by the manufacturer.

(2) A protective, disposable gown.

(3) Either a NIOSH-approved full facepiece respirator appropriate for the hazard; or a less than full facepiece respirator, provided the employee wears a plastic face shield or splash goggles complying with ANSI Z87.1-1989 (see paragraphs 6-3 and 6-4).

b. Isolate the carton and leave it unopened.

c. Place the damaged carton into a closeable, leak-proof, CD waste container as described in chapter 10.

d. Place a hazardous waste warning label on the CD waste container if the CD is a Resource Conservation and Recovery Act (RCRA) (PL 94-580) listed waste (see table 10-1).

e. Transport the closed waste container to a designated CD waste collection area.

f. Wash hands after removing gloves.

g. Notify the shipper immediately.

CHAPTER 8

PHARMACY PREPARATION AREAS

8-1. RESTRICTED AREAS. HCWs should--

a. Prepare CDs in one restricted, centralized area within the pharmacy. If possible, designate an isolated BSC for use when preparing CDs.

b. Minimize the number of HCWs working with these agents and limit access to the CD preparation area to authorized personnel.

c. Keep MSDSs, a CD spill kit, and waste disposal materials in a readily accessible location in or near the preparation area.

8-2. WARNING SIGNS. Post the CD storage area with--

a. A large warning sign bearing the legend:

"CAUTION-RESTRICTED ACCESS - AUTHORIZED PERSONNEL ONLY"

b. A list of all CDs covered by the MTF's HDSHP.

c. A sign detailing procedures for cleaning up and reporting spills as well as procedures for providing first aid after accidental skin and eye contact.

8-3. TRAINING AND SUPERVISION.

a. All pharmacists, technicians, and HCWs who handle CDs should-

(1) Receive information and training as discussed in chapter 3, as well as specialized training in preparing and transporting CDs.

(2) Have a general understanding of BSC design and operation.

b. Pharmacists should regularly observe HCWs working with CDs to ensure compliance with safe work practices.

8-4. PREPARATION.

a. Syringes and IV Sets. If possible, standardize IV equipment with equipment used in the CD administration areas. When handling syringes and IV sets, HCWs should--

(1) Use only syringes and IV sets with Luer-lock fittings since these fittings are less likely to separate during use.

(2) Fill the syringes no more than three-fourths full to prevent drug spillage in the event that the plunger and syringe barrel accidentally separate.

(3) Use large bore needles (i.e., No. 18 or No. 20) to avoid high-pressure syringing of solutions, and use multi-use dispensing pins to minimize dripping from large bore needles.

b. Vials. When withdrawing drug product from vials, HCWs should--

(1) Avoid extreme positive and negative pressure in medication vials.

(2) Use venting devices, such as hydrophobic filter needles or dispensing pins, to provide additional protection and prevent pressure build up in vials by replacing withdrawn liquid with outside air.

NOTE
HCWs must be trained in the proper use of venting devices.

(3) Use a negative pressure technique if venting devices are not available.

(a) Reconstituting.

1. Insert the needle into the vial and slowly add small amounts of diluent down the side of the vial without touching the solution.

2. Alternate addition of diluent with allowance of displaced air to escape into the syringe, thus reducing pressure in the vial.

3. When all diluent has been added, create negative pressure in the vial by withdrawing additional air.

4. Place an alcohol wipe over the needle when withdrawing it from the vial to prevent aerosolization.

5. Because the air in the syringe may contain drug residue, inject it into a vacuum vial or retain the air in the syringe for proper disposal.

(b) Withdrawing Dose.

1. If negative pressure must be applied, draw dose level of air into the syringe and slowly inject and alternately withdraw medication to prescribed dose.

2. Aspirate drug from the needle and hub (neck) prior to separation to prevent spraying.

c. Ampules.

(1) When breaking ampules, HCWs should--

(a) Gently tap down any material from the neck and top portion of the ampule.

(b) Wipe off the outside of the ampule with a 70 percent alcohol wipe.

(c) Wrap sterile gauze or a cotton pledget around the ampule neck to prevent cuts and to capture excess solution.

(d) Hold the ampule away from the face when snapping it open.

(2) When reconstituting dry materials in ampules, HCWs should--

(a) Slowly add diluent down the side of the ampule to avoid splatter of the drug powder.

(b) Use a filter needle to withdraw contents from the ampule to prevent small pieces of glass from being drawn into the syringe.

d. Solid CDs. When handling solid CDs, HCWs should--

(1) Wear one pair of gloves of good quality and thickness.

(2) Count tablets/capsules in a designated CD dispensing area away from the main work area which has minimal air movement (e.g., away from open doors and window, foot traffic, etc.). If there is any possibility that dusts will be generated during the counting process, use a BSC designated for CDs.

(3) Use clean counting equipment dedicated for use with CDs.

(4) Examine CD containers before opening them to detect broken tablets or capsules. If some of the tablets or capsules are broken, carefully remove the desired quantity of the product, keeping any powders in the original container. If too many of the tablets or capsules are broken, return the unopened container to the manufacturer.

(5) Handle gel caps and coated tablets with care to prevent breakage.

NOTE
Gel caps and coated tablets will generally not produce aerosols or dusts unless they are damaged.

(6) Avoid using counting machines unless the process is enclosed to contain any aerosols and dusts that may be generated during the counting process.

(7) Following the counting procedure, rinse the counting tray with plenty of water and swab with 70 percent alcohol; swab the area around the counting tray with moist gauze followed by dry gauze and/or dry sponges.

(8) Place all contaminated cleaning materials and any dropped tablets in a CD waste container.

8-5. PREPARATION IN BIOLOGICAL SAFETY CABINETS. HCWs should--

a. Verify that the BSC is working properly, and notify the proper authorities (i.e., logistics or facilities manager, PVNTMED service, or the contractor if the maintenance has been contracted out) when the BSC is not working properly.

b. Position the moveable sash at the designated height to ensure sufficient airflow and allow comfortable access to the work surface inside the BSC.

c. Adjust stool height so that their faces are above the front opening of the BSC.

d. Wear the following PPE as described in chapter 6:

(1) Two pairs of disposable surgical latex gloves or gloves made of polyvinyl chloride under the latex gloves, a pair of 3-4 mm thick gloves designed specifically for handling CDs, or gloves made of an alternate material recommended by the manufacturer.

(2) A protective, disposable gown.

e. Cover the work surface with a disposable, absorbent, plastic-backed paper liner. Change the liner after any obvious spills and after each work shift.

f. Place the necessary preparation equipment (i.e., a covered sharps container for disposal of contaminated needles, syringes, and other sharp or breakable materials; and a covered container to collect excess CD solutions) inside the BSC before beginning work to minimize disturbance of the laminar airflow.

g. Delay beginning work for about 1 minute after placing hands and arms inside the BSC to allow the BSC to stabilize and to remove surface microbial contaminants from the hands and arms.

h. Keep the front grill free of obstructions by performing manipulations at least 4 inches behind the front grill and by keeping arms slightly raised above the grill.

i. Move arms in and out slowly and perpendicular to the front opening to avoid disrupting the cabinet air barrier.

j. Attach drug administration sets to solutions bags and prime them within the BSC before adding the drug.

NOTE

Priming administrations sets within the BSC before addition of the drug serves two purposes. First, it eliminates the need to prime the set in a less well controlled environment, and second, it ensures that any fluids that escape during priming contain no drug.

k. Immediately place used syringes and needles in a sharps container for disposal to avoid drug aerosolization and needle-stick injuries.

NOTE

NEVER crush, clip, or recap needles or syringes.

l. Place contaminated materials, including used gauze and alcohol wipes, gloves, gowns, and paper liners in a CD waste container.

m. Avoid eating, drinking, smoking, chewing gum or tobacco, applying cosmetics, or storing food in or near the preparation area.

n. Wash hands after removing gloves and before leaving the preparation area.

8-6. TRANSPORTING CYTOTOXIC DRUGS.

a. Before removing CDs from the preparation area, HCWs who prepare CDs should--

(1) Wipe the outside of the prepared drug container with moist gauze or 70 percent alcohol wipes, and wipe entry ports with moist alcohol pads.

(2) Place the securely sealed, capped, or clamped CD containers inside a plastic bag or a leak-proof container for transport.

(3) Label all syringes and IV bags and bottles containing CDs with the patient's name, drug name, quantity per total volume, route of administration, date, time prepared, dose, expiration date, storage requirements, and a warning label bearing the legend:

"CYTOTOXIC DRUG" or "CHEMOTHERAPY"
"SPECIAL HANDLING/DISPOSAL PRECAUTIONS"

b. HCWs who transport CDs should--

(1) Know the procedures for preventing, reporting, and cleaning up CD spills.

(2) Carry the CD containers in a manner to prevent them from falling.

CHAPTER 9

CLINICAL ADMINISTRATION AREAS

9-1. ADMINISTRATION AREAS.

a. Whenever possible, centralize administration areas on inpatient wards and outpatient clinics to ensure the safe handling and disposal of all CDs.

b. Equip administration areas with the administration equipment necessary to facilitate patient care. Also, provide a hand washing sink and emergency eyewash equipment in or near administration areas.

c. Keep MSDSs, a CD spill kit, and waste disposal materials in a readily accessible location in or near the administration area.

9-2. WARNING SIGNS. In the administration area, post a sign detailing procedures for cleaning up and reporting spills as well as procedures for providing first aid after accidental skin and eye contact.

9-3. TRAINING AND SUPERVISION.

a. Only HCWs having specialized knowledge and skills and *who* demonstrate competency in CD administration should be permitted to administer CDs.

b. HCWs who administer CDs should receive information and training as discussed in chapter 3 as well as specialized training in CD administration.

c. Supervisors should regularly observe personnel working with CDs to ensure compliance with safe work practices.

9-4. ADMINISTRATION EQUIPMENT. Keep the following equipment and supplies in a readily accessible location in or near the administration area:

a. Spill towels; absorbent pads; and disposable, plastic-backed, absorbent liners.

b. Sterile gauze pads, tape, and alcohol swabs.

c. Leak-proof linen bags and appropriate warning labels.

9-5. ADMINISTRATION PROCEDURES. HCWs should--

a. Wear the following PPE, as described in chapter 6, when administering CDs or when handling urine, blood, vomitus, and other body fluids from patients who have received CDs in the last 48 hours:

(1) Two pairs of disposable surgical latex gloves or gloves made of polyvinyl chloride under the latex gloves, a pair of 3-4 mm thick gloves designed specifically for handling CDs, or gloves made of an alternate material recommended by the manufacturer.

NOTE

OSHA recommends double gloving, but it is not mandatory if double gloving will interfere with HCW's administration technique.

(2) A protective, disposable gown.

(3) A plastic face shield or splash goggles complying with ANSI Z87.1-1989 whenever splashes, sprays, or aerosols of CDs may be generated.

b. Change gloves at least every hour and immediately change gloves or gowns if they become damaged or contaminated with CDs.

c. Use infusion sets and pumps equipped with Luer-lock fittings or securely tape all connections to prevent accidental separation.

d. Prime IV sets and expel air from syringes in a BSC designated for handling CDs whenever possible. See paragraphs 8-4a and 8-5j for more information on this subject.

NOTE

If priming must be done on the administration unit, use a backflow closed system technique or prime the line with a nondrug-containing compatible flush solution whenever possible. Also, upon completion of administration, flush the line with a nondrug-containing compatible flush solution to clear the IV line. DO NOT use IV containers with venting tubes.

e. Fill syringes no more than three-fourths full when the entire dose is present.

f. Place a plastic-backed absorbent pad under the IV system to absorb potential leakage and to protect the patient when connecting or disconnecting the IV system.

g. Place sterile gauze around IV push sites and tape IV connection sites.

h. Monitor infusion sets for leakage during use.

i. Immediately discard all syringes and needles, empty CD containers and vials, materials contaminated with minuscule droplets, glass IV containers, and glass fragments into a puncture-resistant sharps container.

j. Cap or securely clamp any unused or partially used CDs, place them in a sealable plastic bag, and return them to the pharmacy for disposal.

k. Place linen contaminated with CDs or body fluids from patients having received CDs within the last 48 hours into a specially marked laundry bag which is then placed in a labeled (biohazard symbol or color-coded) impervious bag.

l. Use sterile gauze or 70 percent alcohol wipes to remove drug droplets from infusion pumps, syringes, IV bottles, and bags.

m. Wash surfaces on reusable equipment twice with detergent and rinse them with clean water.

n. Clean protective goggles with detergent and rinse them with clean water.

o. Remove disposable PPE before leaving the administration unit.

p. Wash hands after removing gloves and before leaving the administration unit.

CHAPTER 10

HOUSEKEEPING AND WASTE DISPOSAL

10-1. GENERAL HOUSEKEEPING PROCEDURES.

a. Housekeeping personnel should--

(1) Receive information and training as discussed in chapter 3 as well as specialized training in--

(a) Routine cleaning procedures.

(b) Linen management.

(2) Wear the following PPE, as described in chapter 6, when handling urine, blood, vomitus, and other body fluids from patients who have received CDs in the last 48 hours:

(a) Disposable surgical latex gloves or gloves made of polyvinyl chloride under the latex gloves, a pair of 3-4 mm thick gloves designed specifically for handling CDs, or gloves made of an alternate material recommended by the manufacturer.

(b) A protective, disposable gown.

(c) A plastic face shield or splash goggles complying with ANSI Z87.1-1989 whenever splashes, sprays, or aerosols of CDs may be generated.

(3) Clean reusable face shields and goggles with mild detergent and rinse them with clean water after each use.

(4) Wash hands after removing gloves.

b. Infection control and housekeeping personnel should establish the frequency of routine cleaning of rooms or other work areas or surfaces. Housekeeping personnel should--

(1) Avoid cleaning during CD preparation.

(2) Use the wet mopping technique in CD preparation and administration areas to suppress the formation of dusts.

(3) In the event of a spill, suspend routine cleaning until the area has been properly decontaminated according to procedures described in chapter 11.

c. Trained workers should wash contaminated reusable items and glassware twice with mild detergent and rinse them with clean water. During cleaning procedures, workers should wear a face shield or splash goggles complying with ANSI Z87.1-1989. If splashing is likely, double gloves and a gown should also be worn.

10-2. LINEN MANAGEMENT. Body fluids of patients who have received CDs are potentially hazardous up to 48 hours after drug administration. Blood, urine, stool, and vomitus may contain significant concentrations of the drug or its metabolites.

a. The nursing staff should--

(1) Use disposable linen or absorbable, leak-proof pads for incontinent and vomiting patients.

(2) Manage contaminated disposable linen as regulated medical waste (RMW) unless infection control or oncology personnel decide that it should be managed as CD waste.

b. When handling contaminated reusable linen, housekeeping personnel should--

(1) Handle soiled linen as little as possible and with minimum agitation.

(2) Always bag soiled linen at the location where it was used.

NOTE
Never sort or prerinse soiled linen in patient care areas.

(3) Place linen contaminated with CDs or excreta from patients who have received CDs in the past 48 hours in a specially marked laundry bag which is then placed in a labeled (biohazard symbol or color-coded) impervious bag.

c. Laundry workers should--

(1) Know how to properly handle linens contaminated with CDs.

(2) Wear surgical latex gloves and a nonabsorbent gown when handling contaminated linen before the prewash cycle.

(3) Place the laundry bag and its contents into a laundry machine for a separate prewash, then add it to the other laundry for a second wash.

(4) Follow the same laundering procedures for linens contaminated with bloodborne pathogens.

10-3. WASTE CONTAINERS.

a. RMW Containers.

(1) RMW containers may be used for the disposal of empty CD containers and vials and materials contaminated with minuscule droplets.

(2) RMW sharps containers may be used for disposal of sharps such as needles, syringes, glass IV containers, and glass fragments.

b. CD Waste Containers.

(1) Use scalable, leak-proof plastic containers or heavy-duty, leak-proof plastic bags for disposal of CD waste. If plastic bags are used, keep them inside a covered, waste container clearly labeled with--

"**CYTOTOXIC WASTE ONLY**"

(2) CD waste containers should be specially marked and color-coded differently from general trash, RMW, and other types of hazardous waste containers.

c. Contaminated Container Disposal.

(1) Keep exterior surfaces of waste containers free of contamination as much as possible. If exterior surfaces do become contaminated, place the contaminated container inside a second CD waste container for disposal.

(2) Always store RMW and CD waste containers awaiting disposal in a secure area (i.e., locked area, authorized personnel only, etc.).

10-4. WASTE DISPOSAL. State laws mandate proper disposal of RMW and Federal and state laws mandate the proper disposal of hazardous waste. Improper disposal of such waste is a violation of these laws and may result in criminal or civil charges against the violator. CD

waste must be handled separately from general waste and is usually managed in the same manner as hazardous waste. The preferred method of disposal is to incinerate CD waste in an approved incinerator. Treatment in an autoclave or a retort steam sterilizer will not inactivate the drug and may pose a threat to the health of personnel who operate the equipment. MTFs that generate CD wastes and that treat RMW in a retort steam sterilizer should implement alternative procedures for CD waste disposal such as an agreement with a nearby hospital that has an approved incinerator for burning CD waste or establishing a disposal contract.

a. RMW.

(1) Some hospital-generated wastes are contaminated with minuscule droplets of CDs. Examples include--

(a) Minor splashes or droplets on gloves, gowns, masks, gauze pads, alcohol wipes, and similar items that are contaminated during the preparation and administration of doses and the handling of contaminated linen.

(b) Small spills (see chapter 11).

(c) Completely empty containers that held CDs.

(d) Completely empty syringes and needles used in administering the doses.

(2) HCWs should manage items meeting the above criteria as RMW. Treatment by incineration, autoclave, or retort steam sterilization is acceptable for this category of CD-related waste.

NOTE

If RMW treatment procedures could result in worker exposure to CDs (i.e., aerosolization during autoclaving or steam sterilization), then dispose of CD contaminated materials as CD waste.

b. Hazardous Waste.

(1) Manage the following as hazardous waste:

(a) Excess, unserviceable, expired, and partially full used containers of RCRA-listed CD items.

(b) Wastes from large spills (see chapter 11) and broken containers of RCRA-listed CDs. Other CD waste should be handled as "special waste" (see paragraph 10-6).

(c) Contaminated packaging materials of RCRA-listed CDs. Other CD waste should be handled as "special waste" (see paragraph 10-6).

(2) Table 10-1 lists CDs that the U.S. Environmental Protection Agency (EPA) defines as hazardous wastes under 40 CFR 261.33(f), and they must be managed accordingly.

(a) Regulated items include discarded commercial CD products, off-specification species, container residues, and spill residues. Additionally, specific State regulatory agencies may, at their discretion, list other CD wastes as hazardous wastes. AR 40-5, paragraph 11-6, requires that Army hazardous waste be managed in such a manner as to ensure compliance with appropriate Federal, State, and Department of the Army regulations.

(b) All hazardous waste (including listed CD waste) must be sent to a RCRA permitted hazardous waste incinerator for treatment (under the RCRA regulations, incineration is considered a treatment process not a disposal method).

NOTE
Under no circumstances should CD waste that is regulated as hazardous waste be incinerated in the MTF's RMW or pathological waste incinerator. Treatment of a hazardous waste without a permit is a serious violation of RCRA and brings with it substantial penalties.

(c) CD wastes not specifically regulated by the EPA or applicable State agency as hazardous wastes are not required to be managed as hazardous wastes. AR 40-5, paragraph 11-7c, addresses the specific requirements for the treatment and disposal of health care facility wastes (general, regulated medical, and pathological). If CD wastes (not regulated as hazardous waste) are to be incinerated in the health care facility's RMW or pathological waste incinerator, the incinerator must be permitted as required by State or local air pollution regulations. Additionally, the incinerator must also comply with applicable State and local emission standards and design/operating requirements.

10-5. DRUG DISPOSAL. Any unused drugs, shown in table 10-1, intended for disposal shall be returned to the Pharmacy for an appropriate disposal method.

10-6. COORDINATION. Coordinate waste management procedures with the installation PVNTMED service to assure compliance with applicable regulations and SOPs. PVNTMED

personnel can assist with proper classification of CD wastes (RCRA listed versus "special wastes") and recommend an appropriate disposal method.

Table 10-1. CDs Defined by EPA as Hazardous Wastes

Drug	EPA No.*
CYTOTOXICS	
Azaserine	U015
Chlorambucil (Leukeran)	U035
Cyclophosphamide (Cytoxan, CTX)	U058
Chlornaphazin	U026
Daunomycin (Daunorubicin)	U059
3,3'-Dichlorobenzidine	U073
Diethylstilbestrol (DES)	U089
3,3-Dimethoxybenzidine	U091
p-Dimethylaminoazobenzene	U093
Ethylene Thiourea	Ul 16
Maleic Hydrazine (Maleic Hydrazide)	U148
Melphalan (Alkeran)	U150
4,4-Methylene Bix (2-chloroaniline)	U158
Mitomycin-C (Mutarnycin)	U010
1-Naphthalenamine	U167
Streptozocin (Zanosar, SZNO)	U206
O-tolidine	U328
Uracil Mustard	U237

*These numbers indicate the specific hazardous waste number assigned to these items by EPA.

NOTE: This list is not inclusive of all the agents as there are new products being developed.

CHAPTER 11

SPILLS

11-1. GENERAL. Emergency spill procedures should be a part of the MTF's overall health and safety program. Only those HCWs **SPECIFICALLY TRAINED IN CD SPILL CLEANUP PROCEDURES** should cleanup these types of spills.

11-2. SPILL KITS. CD spill kits are commercially available, but they may be locally made up. The kit should include--

a. Two pairs of surgical latex gloves and a pair of utility latex gloves.

b. A protective, disposable gown as described in chapter 6.

c. Splash goggles and plastic face shield complying with ANSI Z87.1-1989.

d. Shoe coverings.

e. Two or more sheets or spill pads (12" x 12") of absorbent material.

f. 250-milliliters (mL) and 1-liter spill control pillows containing absorbent material.

NOTE
Absorbents should be incinerable.

g. A small scoop or dustpan and a scraper to collect broken glass.

h. Detergent and absorbent gauze pads.

i. A CD waste container or two heavy-duty CD waste bags.

j. A sharps container.

k. One water soluble and one plastic-lined linen bag.

11-3. SMALL SPILLS OUTSIDE THE BIOLOGICAL SAFETY CABINET. For spills of less than 5 mL or 5 grams (gm) outside a BSC, trained HCWs should--

a. Provide first aid to exposed individuals as described in chapter 4.

b. Mark and isolate the spill area so that it is not disturbed by other personnel.

c. Protect themselves from contamination by wearing a gown, two pairs of latex gloves, and splash goggles.

d. Choose an appropriate respirator based on the size of the spill, the drug's chemical properties, the potential for splashing, and the ability to moisten powders before cleaning them up. When there is any danger of the powder becoming airborne or of an aerosol being generated, wear either a NIOSH-approved full facepiece respirator or a less than full facepiece respirator, provided the employee wears a plastic face shield or splash goggles complying with ANSI Z87.1-1989 (see paragraph 11-4). Air-purifying respirators should have a filter designation of at least N95.

e. After letting airborne droplets and dust particles settle, perform the following cleanup procedures:

(1) Pick up broken glass with a small scoop and place broken glass fragments in a small sharps container.

(2) Wipe liquids with a sponge or absorbent gauze pads or wipe solids with wet absorbent gauze pads.

(3) Wash the spill area three times using a detergent solution and rinse with clean water.

(4) Place the sharps container in an RMW container or bag along with the used absorbent pads and contaminated materials.

(5) Follow the instructions in chapter 10 for waste disposal.

(6) Wash reusable items and PPE twice with a mild detergent solution and rinse with water.

f. Document the spill. Spill reports should include--

(1) The name of the agent or drug and approximate volume spilled.

(2) How the spill occurred.

(3) Spill management procedures followed.

(4) Personnel, patients, and others exposed to the spill.

(5) Personnel notified about the spill.

11-4. LARGE SPILLS OUTSIDE THE BIOLOGICAL SAFETY CABINET. For spills of amounts larger than 5 mL or 5 gm, trained HCWs should--

a. Provide first aid to exposed individuals as described in chapter 4.

b. Mark and isolate the spill area so that it is not disturbed by other personnel.

c. Limit the spread as fast as possible by--

(1) Gently covering the spill with absorbent sheets or spill control pads or pillows, or

(2) If a powder is involved, covering the spill with water-dampened cloths or towels.

d. Protect themselves from contamination by wearing two pairs of latex gloves, a gown, and splash goggles.

e. Choose an appropriate respirator based on the size of the spill, the drug's chemical properties, the potential for splashing, and the ability to moisten powders before cleaning them up. When there is any danger of the powder becoming airborne or of an aerosol being generated, HCWs should wear shoe covers and either a NIOSH-approved full facepiece respirator or a less than full facepiece respirator, provided the employee wears a plastic face shield or splash goggles complying with ANSI Z87.1-1989 (see paragraphs 6-3 and 6-4). Air-purifying respirators should have a filter designation of at least N95.

f. Perform the following cleanup procedures after letting airborne droplets and dust particles settle:

(1) Place spill control pads or pillows in a CD waste container.

(2) Pick up broken glass with a small scoop, and place broken glass fragments in a small sharps container.

(3) Wipe liquids with a sponge or absorbent gauze pads or wipe solids with wet absorbent gauze pads.

(4) Wash the spill area three times using a detergent solution and rinse with clean water.

NOTE
Spill cleanup should proceed from the least to the most contaminated areas.

(5) Place the sharps container in an RMW container or bag along with the used absorbent pads and contaminated materials.

(6) Follow the instructions in chapter 10 for waste disposal.

(7) Wash reusable items and PPE twice with a mild detergent solution and rinse with clean water.

g. Document the spill following the procedures described in paragraph 11-3f.

NOTE
All large CD spills outside the BSC should be reported to the hospital safety officer, HAZMAT personnel, and PVNTMED service.

11-5. SPILLS INSIDE THE BIOLOGICAL SAFETY CABINET.

a. For spills less than 150 mL volume, trained HCWs should leave the blower on and follow the procedures for small or large spills as described in paragraphs 11-3 and 11-4.

b. For spills more than 150 mL volume, trained HCWs should leave the blower on and--

(1) Thoroughly clean all interior surfaces, including the spillage trough, three times with detergent and water.

(2) If the spill contaminates the HEPA filter, seal the BSC in plastic and discontinue use until a certified technician can change the filter.

11-6. SPILL MANAGEMENT. Spills and the cleanup residue from CDs, defined by the EPA as hazardous wastes (see table 10-1), must be managed as hazardous wastes (consult with PVNTMED and Logistics for management guidance). Spills and the cleanup residue from CDs that are not defined by EPA as hazardous wastes may be managed as CD wastes and disposed of as RMW.

PART III

AEROSOLIZED DRUGS

CHAPTER 12

PENTAMIDINE

12-1. VENTILATION.

a. Aerosolized pentamidine (AP) therapy should be conducted in a separate negative-pressure treatment room with the door closed. Because of the high potential for exposure to mycobacterium tuberculosis (MTB) during cough inducing and aerosol delivery procedures, the treatment room should be designed and maintained according to OSHA CPL 2.106 or latest standard for preventing occupational exposure to MTB.

b. Local exhaust ventilation, such as properly constructed and vented and/or HEPA filtered booths or hoods, and nebulizers with expiratory filters, such as the Respirgard® II, should be used to contain airborne contaminants at their source.

12-2. ADMINISTRATIVE CONTROLS.

a. Training and Education. All HCWs who administer AP should receive information and training as discussed in chapter 3 and specialized training in--

(1) The proper use of the nebulizer delivery system and local exhaust booths or hoods.

(2) AP administration procedures.

(3) Infection control and precautions for preventing occupational exposure to MTB.

b. Warning Signs. Before beginning AP therapy, HCWs, should install a warning sign at the treatment room entrance to warn all who enter, including visitors, of the potential hazards. Nonessential HCWs should avoid entering the treatment room during AP administration.

c. Nebulizers. HCWs should turn off the nebulizer 2-5 minutes before removing the mouthpiece from the patient. In addition, HCWs should instruct patients to turn off nebulizers when they need to remove the mouthpiece during AP therapy.

®Respirgard is a registered trademark of Marquest Medical Products, Inc. Englewood, Colorado.

d. Spill Cleanup. In the event of a spill, a trained HCW should--

(1) Put on appropriate PPE (see paragraph 12-3).

(2) Dampen the solid spill material with water or wipe up liquids with absorbent material.

(3) Transfer the spill material to an appropriate waste container.

(4) Wipe the area with absorbent paper dampened with water to pick up any remaining material, and then wash all contaminated surfaces with soap and water.

(5) Place contaminated disposable clothing in a sealable plastic bag for disposal.

(6) Document the spill. Spill reports should include--

(a) The name of the agent or drug and approximate volume spilled.

(b) How the spill occurred.

(c) Spill management procedures followed.

(d) Personnel, patients, and others exposed to the spill.

(e) Personnel notified about the spill.

e. First Aid.

(1) Skin Contamination. Immediately rinse affected skin with water, remove contaminated clothing, and wash affected skin with soap and water for 15 minutes.

(2) Eye Contamination. Remove contact lenses, if present, and flush eyes with water for 15 minutes.

(3) Inhalation. Immediately leave the contaminated area and take deep breaths of fresh air. Give cardiopulmonary resuscitation if required.

(4) Ingestion. Do not induce vomiting. If the victim is conscious and not convulsing, give him/her one to two glasses of water to drink. Contact your local poison control center for additional instructions.

f. Pregnancy Policy. Women should avoid exposure to pentamidine during pregnancy and within 8 weeks of becoming pregnant. Pregnant HCWs and HCWs who are trying to conceive a child should be given the option of being transferred to other comparable duties that do not involve handling pentamidine.

g. Waste Disposal. Waste should be disposed of in accordance with Federal, State, and local regulations.

12-3. PERSONAL PROTECTIVE EQUIPMIENT. Whenever there is potential for eye or skin contact or inhalation of dusts, fumes, mists, or vapors, HCWs should wear--

a. Splash goggles complying with ANSI Z87.1-1989.

b. Surgical latex gloves.

NOTE

HCWs with known or suspected latex sensitivity should wear gloves made of an alternate material recommended by the manufacturer or gloves made of polyvinyl chloride under the latex gloves.

c. Long-sleeved disposable gowns.

d. At a minimum, a NIOSH-approved, air-purifying, particulate respirator with a filter designation equal to N95 or N100 (i.e., 3M® Company respirator models 8212 or 8233 or an equivalent model), or consult the Installation Respiratory Protection Program Manager or PVNTMED service personnel to determine the appropriate type of respirator and filter.

NOTE

Use respirators in accordance with OSHA (29 CFR 1910.134) and Army (AR 11-34) regulations. Select particulate respirator filters in accordance with NIOSH (42 CFR 84).

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CHAPTER 13

RIBAVIRIN

13-1. VENTILATION.

a. Ribavirin inhalation therapy should be conducted in a separate negative-pressure room with the door closed. The room should have at least six air changes per hour.

b. An aerosol generator, such as the Small Particle Aerosol Generator Model-2 (SPAG-2), along with a vacuum scavenger system should be used to aerosolize ribavirin.

13-2. ADMINISTRATIVE CONTROLS.

a. Training and Education. All HCWs who administer ribavirin should receive information and training as discussed in chapter 3 and specialized training in--

(1) Proper use of the aerosol generator and vacuum scavenger systems.

(2) Ribavirin administration procedures.

b. Warning Signs. Before beginning therapy, HCWs should install a warning sign at the treatment room entrance to warn all who enter, including visitors, of the potential hazards. Nonessential HCWs should avoid entering the room during ribavirin administration.

c. Aerosol Generators. HCWs should turn off the aerosol generator when attending patients and while handling the respiratory equipment.

d. Spill Cleanup. In the event of a spill, a trained HCW should follow the procedures listed in paragraph 12-2d.

e. First Aid. In the event of an exposure to ribavirin, HCWs should follow the procedures listed in paragraph 12-2e.

f. Pregnancy Policy. Pregnant HCWs and HCWs who are trying to conceive a child should be given the option of being transferred to other comparable duties that do not involve handling ribavirin.

g. Waste Disposal. Waste should be disposed of in accordance with Federal, State, and local regulations.

13-3. PERSONAL PROTECTIVE EQUIPMENT. Whenever there is potential for eye or skin contact or inhalation of dusts, fumes, mists, or vapors, HCWs should wear--

a. Splash goggles complying with ANSI Z87.1-1989.

b. Surgical latex gloves.

NOTE
HCWs with known or suspected latex sensitivity should wear gloves made of an alternate material recommended by the manufacturer or gloves made of polyvinyl chloride under the latex gloves.

c. Long-sleeved disposable gowns.

d. At a minimum, a NIOSH-approved, air-purifying, particulate respirator with a filter designation equal to N95 or NI00 (i.e., 3M Company respirator models 8212 or 8233 or an equivalent model), or consult the Installation Respiratory Protection Program Manager or PVNTMED service personnel to determine the appropriate type respirator and filter.

NOTE
Use respirators in accordance with OSHA (29 CFR 1910.134) and Army (AR 11-34) regulations. Select particulate respirator filters in accordance with NIOSH (42 CFR 84).

PART IV

APPENDICES AND GLOSSARY

APPENDIX A

REFERENCES

A-1. ARMY REGULATIONS.

AR 11-34	The Army Respiratory Protection Program
AR 40-2	Army Medical Treatment Facilities: General Administration
AR 40-5	Preventive Medicine
AR 40-7	Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances
AR 385-40	Accident Reporting and Records

A-2. TB MED.

TB MED 510	Guidelines for the Control and Evaluation of Occupational Exposure to Waste Anesthetic Gases

A-3. OTHER PUBLICATIONS.

American National Standards Institute (ANSI) Z9.5-1992	American National Standard for Laboratory Ventilation
ANSI Z87.1-1989	American National Standard Practice for Occupational and Educational Eye and Face Protection
ANSI Z358.1-1998	American National Standard for Emergency Eyewash and Shower Equipment
DHHS Publication No. 93-8395	Biosafety in Microbiological and Biomedical Laboratories

DHHS (NIOSH) Publication No. 97-135	NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace
NIOSH Publication No. 88-119	Guidelines for Protecting the Safety and Health of Health Care Workers
NSF International Standard 49	Class II (Laminar Flow) Biohazard Cabinetry
OSHA Instruction TED 1.15	U.S. Department of Labor, Occupational Safety and Health Administration: OSHA Technical Manual. Washington, D.C., OSHA 1995
OSHA CPL 2.106	Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis. Washington, D.C., OSHA 9 February 1996
PL 91-596	Occupational Safety and Health Act of 1970
PL 94-580	Resource Conservation and Recovery Act of 1976
USAEHA TG No. 126	Waste Disposal Instructions
29 CFR 1910	Occupational Safety and Health Standards
40 CFR 261	Identification and Listing of Hazadous Waste
40 CFR 264	Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
40 CFR 265	Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
42 CFR 84	Approval of Respiratory Protective Devices
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antineoplastic drug handlers. Am. J. Hosp. Pharm. 47:1061-6

Unnumbered National Institutes of Health (NIH) Warren Grant Magnuson Clinical Center Nursing Department. *Safe Handling and Disposal of Hazardous Drugs*. Bethesda: NIH. 1997.

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Unnumbered "Respiratory Effects of Occupational Exposure to Aerosolized Pentamidine," Journal of Occupational Medicine, Volume 37, Number 2 (February 1995): 145-150.

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Unnumbered Tweedy, J. T. (1997). Healthcare Hazard Control and Safety Management. Delray Beach: St. Lucie Press.

A-4. FORMS.

DA Form 2028	Recommended Changes to Publications and Blank Forms
OSHA No. 200	Log and Summary of Occupational Injuries and Illnesses

APPENDIX B

SAMPLE HAZARDOUS DRUG SAFETY AND HEALTH PLAN

B-1. This appendix contains a copy of a U.S. Army Medical Department Activity (MEDDAC), Fort Riley memorandum (FR MEDDAC Memo No. 40-122).

B-2. USACHPPM considers this memorandum a good source to be used as a sample HDSHP. OSHA was given an opportunity to review the memorandum, and they provided a few comments. USACHPPM feels that OSHA's comments are valid; therefore, those comments are inserted in italics within the appropriate paragraphs of the memorandum.

NOTE: DD Form 1348 is obsolete and has been replaced by DD Form 1348-1A.

DEPARTMENT OF THE ARMY
HEADQUARTERS, USA MEDICAL DEPARTMENT ACTIVITY
Fort Riley, Kansas 66442-5037

FR MEDDAC Memo No. 40-122
Medical Services

HANDLING OF CYTOTOXIC MATERIALS AND HAZARDOUS DRUGS

1. HISTORY. This is the second printing of this document.

2. PURPOSE. To establish policy and procedures for safe handling of cytotoxic (anti-neoplastic or chemotherapy) and other hazardous drugs at Irwin Army Community Hospital, Fort Riley, Kansas.

3. REFERENCES. See Appendix A for list of references.

4. SCOPE. This regulation is applicable to all personnel involved with the procurement, storage, preparation, distribution, administration, and disposal of hazardous drugs (HDs) and materials contaminated with these substances.

5. GENERAL. Cytotoxic drugs (CDs) are an integral part of both inpatient and outpatient treatment regimens for many cancers. Their effectiveness is due to their toxicity to cancerous cells in the body. Cytotoxic drugs also adversely affect healthy cells in patients and health care providers. Fortunately, the risk to health care providers and others who must work with cytotoxic drugs and their waste can be minimized or eliminated by developing and following standard procedures for preparing, administering, disposing, and handling these drugs, and by providing engineering controls when available.

6. RESPONSIBILITIES.

OSHA's Review Comment - It appears that different individuals have been designated as having the responsibility of ensuring that drugs are handled and disposed of safely in their particular areas. However, I do not find any mention of overall coordination of these activities. For example, different people are responsible for providing training. Efforts should be made to assure that training includes the same information for all trainees, with some added information depending on location-specific work. A coordinated approach with meetings arranged between those with program responsibilities would help assure that all workers receive uniform information about these hazards and their control.

a. Chiefs of Departments/Services/Sections that handle CDs will ensure compliance with regulations and guidance governing CD handling, training, and disposal.

b. Deputy Commander for Clinical Services (DCCS) will:

(1) Ensure the establishment of a training program for physicians who will handle and administer CDs.

(2) Ensure each clinic/ward level has a standard operating procedure for physicians who administer CDs.

c. Deputy Commander for Nursing Services (DCNS) will:

(1) Ensure the establishment of a training program for nursing personnel who will handle and administer CDs.

(2) Ensure each clinic/ward level has a standard operating procedure for nursing personnel that administer CDs.

(3) Ensure each clinic/ward maintains Material Safety Data Sheets (MSDSs) for HDs handled in that area.

(4) Maintain a log of nursing personnel preparing and administering HDs, dates of preparation and drugs prepared.

d. Chief, Pharmacy Service will:

(1) Function as the hazardous drug officer.

(2) Review and evaluate FR MEDDAC Memo 40-122 in conjunction with Preventive Medicine Service for effectiveness at least annually. Provide the safety committee with the results of the annual review. Update FR MEDDAC Memo 40-122 in conjunction with Preventive Medicine Service as necessary.

(3) Submit reports of spills, exposures, and other incidents involving CDs to the safety committee for review IAW the hospital's information collection and evaluation system (ICES). Implement the safety committee's recommendations regarding safe use, handling, and disposal of HDs.

(4) Review and approve all proposals for introducing experimental CDs into the workplace.

(5) Ensure safe work practices and appropriate engineering controls are instituted and maintained in all areas where CDs are present.

(6) Ensure personnel preparing CDs are trained appropriately.

(7) Maintain MSDSs along with other relevant information on the toxicity, acute exposure treatment, chemical inactivators, solubility and stability of all CDs used in the facility. MSDSs may not be available for products in solid final form for direct administration to patients.

(8) Maintain a log of personnel preparing CDs, dates of preparation, and drugs prepared.

(9) Maintain hazardous chemotherapy waste satellite accumulation point (SAP) IAW Fort Riley Hazardous Waste and Controlled Material Management SOP, and conduct weekly inspections of that SAP.

(10) Ensure that CDs are received and stored in accordance with this regulation, and other appropriate guidelines.

(11) Maintain an adequate inventory of chemotherapy waste containers, labels, and supplies for handling hazardous chemotherapy waste.

(12) Ensure proper labeling, preparation, and handling of all hazardous chemotherapy waste containers, completion of DD Form 1348-1A (turn-in document), and include material safety data sheets.

(13) Coordinate with Logistics Division, Medical Supply, for transport of full hazardous chemotherapy waste containers within 72 hours of notification from the pharmacy to the < 90 day storage area in the logistics, warehouse.

(14) Coordinate with Housekeeping for disposal of waste chemotherapy preparation and administration material (WCPAM). This material will be transported by trained pharmacy personnel and burned in the hospital incinerator.

e. Logistics Division.

(1) Chief, Medical Supply will:

(a) Ensure proper labeling, preparation, and handling of all hazardous chemotherapy waste containers and proper completion of DD Form 1348-1A.

(b) Maintain the < 90 day storage area for hazardous waste IAW the Fort Riley Hazardous Waste Management and Controlled Material Management SOP and FR MEDDAC Reg 200-2, Hazardous Waste Management Program, state, and federal regulations; and conduct weekly inspections of the storage area.

(c) Arrange for disposal of all chemotherapy waste IAW this regulation, Directorate of Resource Management Office (DRMO), Fort Riley Hazardous Waste and Controlled Material Management SOP, state and federal regulations.

(2) Chief, Medical Maintenance Branch will ensure that biological safety cabinets (BSCs) used for the preparation of CDs are certified and maintained in accordance with the National Sanitation Foundation (NSF) Standard 49, Class II (Laminar Flow Biohazard Cabinetry. Certification must occur at least semi-annually and whenever the BSC is moved or repaired.

f. Preventive Medicine Service.

(1) Occupational Health Section will:

(a) Conduct initial and annual medical surveillance for employees who handle CDs.

(b) Maintain exposure records on all employees handling these substances for the duration of employment plus 30 years.

(c) Evaluate workers following acute exposures, with documentation in each Occupational Health record.

(2) Environmental Health Section will:

(a) Monitor CDs storage, handling, and disposal.

(b) Maintain a log of chemotherapy spills.

(3) Environmental Science Officer will determine disposal methods and procedures for all chemotherapy wastes.

g. Safety Manager will help supervisors investigate all accidents/incidents involving CDs and record/report all occupational injuries and illnesses as required.

h. Risk Manager will keep each DA Form 4106, Quality Assurance/Risk Management Report, used to report an incident with CDs.

i. Supervisors of personnel handling CDs will:

(1) Conduct orientation training for all employees handling CDs, to include spill cleanup procedures.

(2) Conduct training on changes in CD handling policies and procedures, and when new CDs are introduced.

(3) Ensure all employees report for medical surveillance before they start working with CDs, annually, and upon termination of employment or work with CDs.

(4) Ensure Occupational Health is notified of any changes in status of personnel working with CDs.

(5) Evaluate employee compliance with CD handling procedures and retrain as necessary.

(6) Maintain a record of all employee training. Hazardous drug training records shall be kept for three years following training.

(7) Develop specific SOPs where necessary for handling and disposal of both CDs and WCPAM. These SOPs should include,points of contact and phone numbers, supply locations, and waste container locations. The only locations authorized for administration of CDs are Ward 2A, Pediatric Clinic, and the Medical Clinic. Dermatology will utilize the Medical Clinic when administering CDs.

(8) Ensure the administration of CDs occurs only at authorized locations unless coordinated with Environmental Health, Preventive Medicine Service.

(9) Ensure proper segregation and disposal of hazardous chemotherapy waste and WCPAM.

(10) Staff site specific SOPs through Environmental Health, Preventive Medicine Service.

(11) Replace full containers with a properly prepared empty container (see Appendix B).

(12) Ensure engineering controls located in areas under their responsibility are operable.

(13) Ensure workers have appropriate personal protective equipment (PPE) and that workers are trained in the PPE's limitations, maintenance, and use.

(14) Investigate and report all spills, exposures, and incidents involving CDs.

(15) Establish designated locations within their work area(s) for CD storage and use. Access to designated locations are restricted to authorized personnel.

j. The NCOIC of the Medical Clinic will coordinate with Housekeeping for disposal of WCPAM. This material will be transported by the NCOIC and burned in the hospital incinerator.

7. PROCEDURES.

a. Information, Training and Competency.

(1) Information, training, and competency evaluations are supervisory responsibilities.

(2) All personnel involved in handling or potentially contacting CDs in the hospital will receive information and training to alert them of the hazards. Personnel will receive information and training at the time of initial assignment and prior to assignments involving new hazards. Personnel will attend refresher information and training at least annually.

(a) Information will include any operation or procedures in the work area where CDs are present and the location and the availability of the written hazard communication program and work area CD safety SOPs.

(b) At a minimum, training must include the methods and observations used to detect the presence or release for CDs in the work area; the physical and health hazards, with emphasis on the reproductive hazards; the measures that will protect personnel form CD hazards, including precautions for handling, storing, using, and disposing of CDs; personal protective equipment; hazard communication, including an explanation of labeling systems and MSDSs and spill incident reporting procedures; provisions for obtaining medical examinations and emergency procedures after an acute exposure.

(3) Personnel competency must be evaluated after initial orientation and training and at least annually thereafter. Evaluation results must be documented in departmental personnel competency folders.

(4) Training records must be maintained for at least three years from the date on which training occurred. At least, training records must include: the dates of the training sessions; and outline or summary of the information presented, the names and qualifications of persons conducting the training, and the names and job titles of all persons attending the training.

b. Medical Surveillance.

(1) All employees potentially exposed to CDs as part of their routine responsibilities will have a preplacement examination. Cytotoxic drug related tasks include preparation, administration, waste disposal, transport, storage, and spill cleanup. This exam should include a complete blood count with differential to establish a baseline.

(2) All employees working with CDs will receive annual medical surveillance through Occupational Health.

(3) A physical exam and appropriate follow up will be performed for any acute exposure to CDs and when personnel shows signs or symptoms associated with CD exposure(s). Acute exposures are: a needle stick from a needle attached to a syringe or IV catheter containing a CD; a spill or splash into the eyes or on exposed skin; or any other suspected exposure. Acute exposures will be recorded in the employee's medical record, and on the appropriate safety and personnel forms. Any occurrence of exposure related disease or adverse health effects requires an immediate reevaluation of engineering controls, administrative controls, and PPE to assess their appropriateness and effectiveness.

(4) Occupational Health coordinates routine annual medical surveillance with supervisors. Non-routine medical surveillance (pre-placement, pregnancy, acute exposure) will be coordinated by the employee's supervisor.

(5) Pregnancy.

(a) The initial physical exam and job related CDs training will include informing the employee of the potential reproductive effects of CDs.

(b) Pregnant or breast feeding staff members should be screened by Occupational Health as soon as their pregnancy is known. Pregnancy screening is optional for Department of the Army Civilian employees (DAC), mandatory for military staff members. They will be informed of the potential reproductive effects of CDs and told of their right, without punitive

impact, to request assignment to duties not involving CD handling. This choice will be documented in writing. If a DAC chooses not to be screened by Occupational Health, the supervisor will ensure they are counseled, indicate their choice and sign a statement. A sample statement which meets this requirement is at appendix C. Occupational Health will maintain a copy of the signed form in the individual's medical record. This limitation of duties will occur as soon as possible, but will be in effect no more than five working days from date of request. Employees will be allowed to change their choice at any time, also effective within five working days.

(c) Male or female employees actively tying to conceive a child will also be given the choice of whether they wish to be assigned to duties not involving CDs.

c. Storage and Transport.

(1) Access to CDs storage area will be limited to authorized personnel. These areas will be posted with warning signs bearing the legend: "CAUTION--CHEMOTHERAPY DRUGS." Cytotoxic drug storage will be in a manner that prevents containers from falling.

(2) Damaged shipping cartons should be isolated and left unopened by receiving personnel. The shipper will be notified immediately. Only personnel trained to work with CDs will handle damaged shipping cartons. When handling damaged shipping cartons, personnel will wear Chemo Plus latex gloves, closed gown, eye protection, and a National Institute for Occupational Safety and Health (NIOSH) approved respirator. Personnel will NOT OPEN damaged cartons. Instead, personnel will place the damaged carton into a closeable, impervious waste container with the appropriate waste/warning labels. The closed waste container will be transported to a designated CD waste collection area. Personnel will notify the shipper immediately.

(3) CDs will be transported in a manner that will prevent them from falling or spilling. They will be capped or sealed and placed in impervious packing material for transport.

(4) WCPAM will only be collected in the Inpatient Pharmacy and Medical Clinic. WCPAM, (i.e., gloves, chucks, gowns, completely empty tubing and IV bag) from the Pediatric Clinic, Ward 2A, Dermatology and the Medical Clinic will be collected in the Medical Clinic storage area.

d. Preparation.

(1) Procedures used in the preparation of CDs must comply with the guidance contained in the Occupational Safety and Health Administration (OSHA) Instruction TED 1.15

and recommendations of the American Society of Hospital Pharmacists to include protective equipment use (BSC), and protective clothing worn while preparing CDs.

(2) Preparation area.

(a) All CDs will be prepared by the Inpatient Pharmacy in the biological safety cabinet (BSC) located in the CD preparation area in the basement. Syringes and IV bags will be labeled with the patient's name, drug name and quantity per total volume, route of administration, date and time prepared, dose, expiration date, and storage requirements if the drug is not to be transported immediately. All prepared CD syringes and IV bags will be placed in a large ziplock bag and labeled with a distinctive warning such as "CAUTION CHEMOTHERAPY--IF MEDICATION IS NOT ADMINISTERED TO PATIENT, RETURN TO PHARMACY FOR PROPER DISPOSAL. DO NOT DISCARD ON WARD OR CLINIC."

(b) The BSC and the entrance to the CD prep area will be posted with signs bearing the legend "CAUTION--CHEMOTHERAPY PREPARATION AREA--AUTHORIZED PERSONNEL ONLY," or similar wording.

(c) The BSC must be certified by a qualified technician at least semiannually, after repairs and whenever moved to a new location. The BSC must be certified and maintained in accordance with the National Sanitation Foundation (NSF) Standard 49, Class II (Laminar Flow) Biohazard Cabinetry. A qualified technician knows how the BSC operates, and knows the operational requirements and flow velocities. This person is usually an environmental and industrial hygiene technician or an industrial hygienist.

(d) Employees will be trained in basic BSC design, operations and decontamination procedures.

(3) When handling oral CDs, care must be taken to minimize the generation of dust from the drug. After the counting procedure, rinse the counting tray with copious amounts of water and swab the area around the counting tray with water soaked swabs followed by dry swabs or sponges. All cleaning materials will be bagged in waterproof bags and disposed of in the inpatient pharmacy WCPAM container. All dropped tablets must be retrieved immediately, bagged, labeled as chemotherapy waste (and hazardous waste if appropriate), and disposed of in the appropriate chemotherapy waste container.

e. Administration.

(1) CDs that are ready for administration will be labeled with a unique warning label directly on the drug container (IV bag or syringe) that clearly identifies the contents as chemotherapy. These markings must be clearly visible while the drug is being administered.

(2) Procedures used in the administration of CDs must comply with the guidance contained in OSHA Instruction TED 1.15 and the recommendations of the Oncology Nursing Society.

(3) Only individuals competent in CD administration will be authorized to administer CDs.

(4) Personal Protective Equipment.

OSHA's Review Comment - It is stated that all personnel administering CDs will wear disposable latex gloves. Over the last several years development of latex allergy in health care workers has been of increasing concern. Latex is certainly one choice of gloves. However, it would be prudent to allow for other gloves to be used, in accordance with the drug manufacturer's recommendations. Some testing labs have stated that other gloves have performed better for certain hazardous drugs than the latex gloves they have tested. To allow for the use of other gloves, especially in certain health care facilities that are using alternative gloves, language regarding other types of gloves should probably be included.

(a) All personnel administering CDs will wear disposable latex gloves. The gloves should be powderless, impervious, and designed specifically for HD administration. These latex gloves are 6-7 mils thick, and generally do not require doubling.

(b) Disposable gowns with long sleeves, elastic cuffs, and that close on the back will be worn. While they will not protect from fluids, they will keep any aerosol off personal clothing and skin. Many gowns sold as chemotherapy gowns are water resistant, and will deflect much of a spill away from the wearer.

(c) Face protection, particularly goggles, will be worn.

(5) Aerosolized Drugs.

(a) Ribavirin and pentamidine should be administered only in negative pressure isolation rooms with separate air circulating systems and equipped with high efficiency particulate air (HEPA) filters. Isolation booths with the above features represent an alternative engineering control to the negative pressure room.

(b) Health care workers are required to wear gowns, a NIOSH approved respirator, shoe covers, and latex gloves when there is direct contact with these drugs. This includes entry into the room during nebulization.

(c) Access to patient areas will be limited to essential healthcare personnel only during ribarvirin and pentamidine administration.

f. Personnel Contamination. Contamination of protective equipment or clothing, or direct skin or eye contact will be treated by:

(1) Immediately removing the gloves or gown.

(2) Immediate cleansing of the affected skin with soap and water.

(3) Flooding an affected eye at an eyewash fountain or with water or isotonic eyewash designated for that purpose for at least 15 minutes, for eye exposure.

(4) Obtaining medical attention. Medical attention should also be sought for inhalation of hazardous drugs in powder form.

(5) Documenting the exposure in the employee's medical record.

g. Spills.

OSHA's Review Comment - Present language instructs employee to "Place any broken glass fragments in a small cardboard box or plastic container…," It should be emphasized that these fragments are not to be touched by hand (even a gloved hand) and that some mechanical means (tongs, broom and dustpan, etc.) should be used to place broken glass fragments in the container.

(1) Small spills (less than 10 ml) will be cleaned immediately by personnel wearing gowns, a NIOSH approved respirator (if aerosolization of a HD is possible), eye protection, and Chemo Plus latex gloves. If aerosolization of HD is possible, respirators should be worn as in (2) below. Wipe liquids with plastic-backed absorbent liners; wipe solids with water moistened gauze. The spill area will then be cleaned three times using 70 percent isopropyl alcohol followed by clean water. Place any broken glass fragments in a small cardboard box or plastic container and then place in a CD disposal bag along with the used absorbent pads and any noncleanable contaminated items. All spill cleanup materials from Ward 2A, Pediatric Clinic, Dermatology, Medical Clinic, protective equipment, and residue will be placed in the Medical Clinic WCPAM container. Small spill cleanup material originating in the inpatient pharmacy will be disposed of in the inpatient pharmacy WCPAM container.

(2) Large spills (more than 10 ml) will be cleaned using a chemotherapy spill kit. In addition to the protective equipment listed above, personnel cleaning the spill will wear a NIOSH-approved respirator equipped with HEPA filter when there is any danger of the dust

becoming airborne, or of an aerosol being generated (personnel must have a pulmonary function test, PFT, and a respirator fit test in order to legally wear a NIOSH approved respirator equipped with a HEPA filter and then be monitored as a participant in the Respiratory Protection Program). Waste from cleanup of a large spill will be disposed of as above, unless the drug spilled is a hazardous waste **(as of June 1997, only Chlorambucil USP, Cyclophosphamide NF, Melphalan, and Mutamycin)** which will be placed in a hazardous chemotherapy waste container, labeled, and turned-in to Logistics, Medical Supply for disposal as a hazardous waste.

(3) When a spill occurs, your first priority is to protect yourself and patients. This includes wearing of protective clothing if it is not already wom.

(a) Your second action is to stop the flow of the spill if the spilled container contains any more liquid. This includes setting containers upright, or capping them. If the spill is from a dropped IV bag, it should be carefully picked up by the opening from which the contents have spilled, clamped if possible, and placed in a leakproof bag.

(b) The spill must be contained. This is done by placing absorbent material on, or around the spill. Plastic backed absorbent pads, paper towels, vermiculite, or other absorbent materials can be used to contain the spill.

(c) Once the spill is contained, clean it up, transport the waste to the appropriate collection point or if a hazardous waste, to Logistics, Medical Supply and report the spill as required in paragraph (6) below.

(4) Access to spill sites will be limited to those personnel cleaning it up. Spill areas will be posted with warning signs, and all uninvolved personnel will be directed away from the site.

(5) Spills will be cleaned up by trained personnel using spill kits designed for the cleanup of chemotherapy spills, and paragraphs 7g(2) and (3) of this Memo.

(6) Personnel involved will report all CD spills to the Safety Manager. The initial report can be telephonic, but all spills will be documented in memorandum form. The supervisor of those personnel involved in the incident will initiate DA Form 4106, Quality Assurance/Risk Management Report as required.

(7) Spill kits should contain the following: chemical splash goggles, Chemo Plus latex gloves or other comparable brand, two or more sheets of plastic-backed absorbent material, 250 ml and 1 liter spill control pillows containing absorbent material, a small scoop to collect glass fragments and non-contained absorbent, and two large chemotherapy disposal bags (12x18 to 18x24). Absorbent will be incinerable (i.e. vermiculite).

h. Disposal.

(1) While all CDs are hazardous or controlled materials, they are divided into two categories for disposal purposes; hazardous chemotherapy waste and waste chemotherapy preparation and administration material (WCPAM).

(a) Hazardous chemotherapy wastes are those CD wastes which are listed (or meet the criteria established) by the Environmental Protection Agency as hazardous wastes. Currently **(the only CD in use at IACH that are hazardous wastes are Chlorambucil USP, Cyclophosphamide NF, Melphalan, and Mutamycin).** The **empty** containers and any **empty** equipment/supplies used in handling/preparing these drugs are not hazardous wastes. Empty containers will be placed into a regulated medical waste sharps container. A container is considered empty when all chemical residuals have been removed that can be removed using the practices commonly employed to remove materials from that type of container, e.g. , pouring, pumping, aspirating. A vial containing a few drops of these drugs which cannot be reached with a syringe is considered to be empty. A partially used ampule, or a partially administered dose, full IV bag or tubing, full syringe, of one of these listed and non-listed drugs will be handled as hazardous waste and will be disposed of in the inpatient pharmacy hazardous chemotherapy waste container. Hazardous chemotherapy wastes will be disposed of in a Resource Conservation and Recovery Act (RCRA) permitted hazardous waste incinerator or through commercial contract. Hazardous wastes, as defined here, will NOT be burned in the hospital incinerator.

(b) All other unused, non-listed cytotoxic drugs, A003, SWA1, SWA2, A001, and AC01 will be disposed of according to their assigned disposal codes or containerized with the listed hazardous waste as long as all waste types are annotated on the hazardous waste label. Those HDs listed will be disposed of separately as hazardous wastes. The following are disposal codes for those CDs listed in the pharmacy formulary:

DISPOSAL CODE	NOMENCLATURE	HAZARDOUS WASTE NUMBER	HAZARD CODE
A003	AZATHIOPRINE		
SWAI	BLEOMYCIN SULFATE		
A003	CARBOPLATIN FOR INJ		
HW14	CHLORAMBUCIL USP	U035	T
SWA1	CISPLATIN		
HW14	CYCLOPHOSPHAMIDE NF	U058	T
A003	CYTARABINE (CYTOSAR-U)		
A003	DOXORUBICIN HYDROCHLORIDE		
A003	ESTRAMUSTINE PHOSPHATE		
A001	ETOPSIDE (VEPESID)		
A003	FLUDARABINE PHOSPHATE		
A003	FLUOROURACIL (SYSTEMIC) HYCAMTIN		
AC01	HYDROXYUREA		
AC01	LEUCOVORIN		
SWA1	MECHLORETHAMINE HYDROCHLORIDE USP		
AC01	MEGESTROL ACETATE		
HW14	MELPHALAN	U150	T
A003	MERCAPTOPURINE USP		
SWA1	MUTAMYCIN	U010	T
A003	PROCARBAZINE HCL		
SWA1	TRIETHYLENETHIO-PHOSPHORAMIDE (THIOTEPA)		
A003	THIOGUANINE U.S.P		
A003	VINCRISTINE		
A003	METHOTREXATE USP		
SWA2	TAMOXIFEN CITRATE		

OTHER HDs

DISPOSAL CODE	NOMENCLATURE	HAZARDOUS WASTE NUMBER	HAZARD CODE
HW01	EPHINEPHRINE	P042	H
HW01	PHYSOSTIGMINE SALICYLATE	P188	H
SWA1	DISULFIRAM	U403	T

(Disulfiram vacated U waste in FR Vol. 62, No. 116, Tuesday, June 17, 1997)

AC01 and A001 - May be disposed of in the hospital incinerator as long as the amount does not exceed 1% by weight of the total waste load charged to the incinerator at one time.

A003 , SWA1 & SWA2 - Process through Logistics Division for disposal by commercial contract or through a RCRA permitted hazardous waste incinerator.

HW14 - Process through Logistics Division for disposal by commercial contract. This item is a hazardous waste under 40 CFR 261.33(f).

HW01 - This item is listed as a hazardous waste according to 40 CFR Part 261. Standard paragraph 4 (RCRA waste); contract disposal with permitted disposal firm.

(c) WCPAM material include the following items: completely empty IV bags, tubing, chucks, gloves, disposable aprons, and material from spills of < 10ml of a CD. WCPAM syringes must be disposed of in a regulated medical waste sharps container.

(d) State and federal laws mandate proper disposal of special waste and hazardous wastes. Improper disposal of such waste is a violation of these laws and may result in criminal charges and substantial monetary fines against the violator.

(2) Each section administering chemotherapy drugs will return the ziplock bag with unused CD to the inpatient pharmacy for proper disposal as hazardous chemotherapy waste.

(3) The inpatient pharmacy will have a container for disposal of hazardous chemotherapy waste in addition to a WCPAM container. The area holding the hazardous chemotherapy waste container is considered a satellite accumulation point (SAP) and will comply with the Fort Riley Hazardous Waste and Controlled Management SOP requirements for SAPs.

(4) When a hazardous chemotherapy waste container is full, seal, date, and coordinate with Logistics Division for removal to the < 90 day storage area. The full container must be moved to Logistics Warehouse within 72 hours. Obtain a new container and prepare per Appendix B.

(5) Full chemotherapy waste containers will be stored in the Logistics Division < 90 day storage area for hazardous wastes. This storage area will comply with the requirements for hazardous waste. Questions on which type of waste a specific item is should be directed to the Environmental Science Officer.

(6) Appendix B and B-1 describe the requirements for hazardous waste chemotherapy and WCPAM containers.

(7) All body fluids, secretions, or excretions from patients who have received CD in the last 72 hours should be considered to contain CD or their metabolites. Personnel handling patient blood, vomitus, feces and urine from patients receiving hazardous drugs within the previous 72 hours will wear gowns and latex gloves. Eye protection should be worn if splashing is possible.

(a) Personnel handling these materials will wear protective equipment worn in administering the drugs. Linens contaminated with body fluids will be handled as infectious linen.

(b) Free flowing body fluids and waste will be flushed to the sewer.

(c) When these materials are spilled on hard surfaces, they will be mopped up or absorbed on pads. The affected areas will then be cleaned with 70% isopropyl alcohol. Mop water will be flushed to the sewer; disposable cleanup materials (sponges, absorbent pads) will be disposed of in the waste chemotherapy preparation and administration material container.

(d) Clothing contaminated by CD contaminated body fluids will be removed as soon as possible, bagged in a water proof bag and laundered with bleach.

(8) Excreta contaminated with blood or other potentially infectious material must be managed according to OSHA's Bloodborne Pathogens Standards.

(9) Linen contaminated with hazardous drugs should be handled in a manner similar to that for linen contaminated with infectious agent.

The proponent of this regulation is Preventive Medicine Service, USA MEDDAC. Send comments and suggested improvements to Commander, USA MEDDAC, ATTN: MCXX-PMS, Fort Riley, KS 66442-5037.

FOR THE COMMANDER:

OFFICIAL:

GLEN C. SIMPSON, JR.
LTC, MS
Deputy Commander for Administration

MICHELINE M. FIELDS
C, Information Management Division

Appendices
a - References
B - Hazardous Chemotherapy Waste Handling Procedures
B- 1 -Waste Chemotherapy Preparation and Administration Material Containers
C - Statement Pertaining to Employment of Persons in Positions Involving Cytotoxic Drug Handling

DISTRIBUTION:
A

APPENDIX A

REFERENCES

1. AR 40-5, Preventive Medicine.

2. AR 420-49, Facilities Engineering, Utilities Services.

3. Kansas Statutes Annotated, Chapter 65-Public Health, Article 34-Hazardous Waste, and Administrative Regulations, Article 3 1 -Hazardous Waste Management.

4. Fort Riley Hazardous Waste & Controlled Material Management SOP.

5. Occupational Safety and Health Administration Instruction TED 1.15.

6. Brune, Dag K., and Endling, Christer. Occupational Hazards in the Health Professions. CRC Press, Boca Raton, FL. 1989.

7. NIOSH. Guidelines for Protecting the Safety and Health of Health Care Workers. U.S. Government Printing Office, Washington, DC. 1988.

8. NSF International Standard 49, Class II (laminar Flow) Biohazard Cabinetry, National Sanitation Foundation, Ann Arbor, Michigan, 1987.

9. Title 40 Code of Federal Regulations, Protection of Environment, Part 261, published by the Office of Federal Register National Archives and Records Administration, 1996.

APPENDIX B

HAZARDOUS CHEMOTHERAPY WASTE HANDLING PROCEDURES

1. Inpatient Pharmacy is the only authorized location for hazardous chemotherapy waste drug collection.

2. All collection containers will be approved by the Environmental Science Officer to ensure they are suitable for the type of waste and meet Environmental Protection Agency and Department of Transportation requirements.

3. The plastic hazardous chemotherapy waste container will be prepared as follows:

a. Two inches of vermiculite will be added to the inside of the bucket to absorb any liquid.

b. The top and side of the bucket will be labeled with a hazardous waste label. The label name will read "Chemotherapy Waste". The accumulation start date, and manifest document number blocks are **left blank.**

c. No lining is required because the bucket is leak proof.

4. Hazardous chemotherapy waste containers will not be labeled until they are put into use.

5. The hazardous chemotherapy waste container must remain covered except when waste is being placed into it.

6. When the hazardous chemotherapy waste container in the Inpatient Pharmacy is full, conduct the following:

OSHA's Review Comment - Instructions are provided for the occasion when the hazardous chemotherapy waste container is full. A plan should be in place so that when a particular container is full, another container can be readily put in position for use. A practical approach could be to prepare a second container for use when the first container is half or ¾ full so that the second container can immediately be placed into use as the first one is sealed. In this manner, the likelihood that one container will be in the process of being sealed up for disposal while the replacement container has not yet been prepared is greatly reduced.

a. Ensure the container is sealed and marked with the date the container became full. Complete a DD Form 1348-1 (turn-in document), include material safety data sheets, and attach a list of all CDs which were placed into the container.

b. Coordinate within 72 hours with Logistics for transfer of the full container to the Logistics warehouse < 90 day storage area.

c. Verify that the container is properly labeled and prepared.

d. Replace the container with a new labeled one and prepare with vermiculite per paragraph (3) above.

7. An Environmental Team must be appointed on orders and trained. The team must have a primary team leader and team member. There must also be a trained alternate team leader and team member. The Environmental Team responsibilities are outlined in the Inpatient Pharmacy site file.

8. The hazardous waste site file must be maintained, located near the collection site, and available for inspection.

APPENDIX B-1

WASTE CHEMOTHERAPY PREPARATION AND ADMINISTRATION MATERIAL CONTAINERS

1. The only authorized locations for WCPAM containers are the Inpatient Pharmacy and Medical Clinic.

2. The WCPAM container will be a designated, covered, waste receptacle with a yellow inner plastic liner. The waste receptacle will be labeled with the words "CAUTION: WASTE CD PREP & ADMIN MATERIAL". When the container is full, seal the bags with tape.

3. The Medical Clinic will have a container for WCPAM. This container will be the central location for collection of WCPAM from Ward 2A, Pediatric Clinic, Dermatology, and the Medical Clinic.

4. The Inpatient Pharmacy will have a container for WCPAM.

5. A trained member of the Inpatient Pharmacy Environmental Team will transport WCPAM from the Inpatient Pharmacy and load it into the incinerator in coordination with Housekeeping as needed.

6. The NCOIC, Medical Clinic, will transport WCPAM from the Medical Clinic and load it into the incinerator in coordination with Housekeeping as needed. The NCOIC will receive awareness training on the hazards of chemotherapy drugs.

APPENDIX C

STATEMENT PERTAINING TO EMPLOYMENT OF PERSONS IN POSITIONS INVOLVING CYTOTOXIC DRUG HANDLING

Employee_____ Duty Section_____

1. Although there is no conclusive evidence, at least one study has reported a statistically significant association between fetal loss in the first trimester and occupational exposure to cytotoxic drugs.

2. Cytotoxic drugs work as a result of their ability to disturb growth and kill tumor cells by interfering with biochemical pathways. The selectivity of the drug between cancer and normal cells depends on differences in activity of these pathways. Rapidly dividing cells, such as cancer cells, cells from bone marrow, hair follicles, testes, ovaries, and fetus are more affected by cytotoxic drugs than other cells are. Mutagenic, carcinogenic, and teratogenic effects of cytotoxic drugs have been well docurnented.

3. Wearing personal protective equipment and following proper procedures in handling cytotoxic drugs greatly reduces the risk to workers and their babies, however, this risk is never zero. Therefore, all pregnant or breast-feeding women, and men or women actively trying to conceive a child are given the choice of whether they wish to be assigned to duties not involving cytotoxic drugs for the duration of these circumstances. Assignment to duties not involving cytotoxic drugs will normally occur within your current work unit. Limitation of duty will occur as soon as possible, but will be in effect no more than five working days from date of request.

4. Should you become pregnant, breast-feed your child, or decide to try to conceive, the decision to accept the risks of working in a position handling cytotoxic drugs is yours. If you have any questions or concerns, you are urged to consult your obstetrician, family physician, or a knowledgeable physician on our staff.

5. Regardless of your decision, you have the option to change your choice. Once again, the limitation of duty will be effected as soon as possible; and will be no more than five working days from date of request.

Acknowledgment:

I have read and I understand the above statement pertaining to the employment of pregnant or breast-feeding women, and men or women actively trying to conceive a child, who work in positions involving the handling of cytotoxic drugs. I understand that any exposure to cytotoxic drugs may increase the risk of bearing children with congenital abnormalities or having a spontaneous abortion. I further understand that if I become pregnant, breast-feed, or decide to try to conceive a child, I have the option of working in a position that will not involve my handling of chemotherapy drugs.

Mark your choice by initialing the space in front of the appropriate statement below.

_____I agree to continue to work in my present capacity, and continue to handle cytotoxic (also called antineoplastic or chemotherapy) drugs.

_____I request limitation of my duties to tasks that do not require the handling of cytotoxic drugs for the duration of my circumstance (pregnancy, breast-feeding, or attempting to conceive).

_____	_____	_____
(Employee Signature)	(Date)	(Supervisor or OH Signature)

GLOSSARY

ABBREVIATIONS

ANSI	American National Standard Institute
AP	aerosolized pentamidine
AR	Army Regulation
BSC	biological safety cabinet
CD	cytotoxic drug
CFR	Code of Federal Regulations
DHHS	U.S. Department of Health and Human Services
DSN	Defense Switching Network
EPA	U.S. Environmental Protection Agency
fpm	feet per minute
gm	gram
GRAS	generally regarded as safe
HAZCOM	hazard communication
HAZMAT	hazardous material
HCW	health care worker
HD	hazardous drug
HDSHP	hazardous drug safety and health plan
HEPA	high efficiency particulate air
IV	intravenous
mm	millimeter
mL	milliliter
MSDS	material safety data sheet
MTB	mycobacterium tuberculosis
MTF	military treatment facility
NIOSH	National Institute for Occupational Safety and Health
NSF	National Sanitation Foundation
OSHA	Occupational Safety and Health Administration

PL	Public Law
PPE	personal protective equipment
PVNTMED	preventive medicine
RCRA	Resource Conservation and Recovery Act
RMW	regulated medical waste
SOP	sanding operating procedure
SPAG	Small Particle Aerosol Generator
TB MED	Technical Bulletin, Medical
TG	Technical Guide
USACHPPM	U.S. Army Center for Health Promotion and Preventive Medicine
WAG	waste anesthetic gases